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THE PITUITARY CONNECTION

NEWSLETTER OF THE AUSTRALIAN PITUITARY FOUNDATION LTD

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MISSION STATEMENT

The APF's mission is to provide support to those who have experienced pituitary gland conditions. We promote awareness and disseminate information helpful to the medical community, public, pituitary patients and their families.

IN THIS ISSUE

FEATURE ARTICLE -

X-LINKED ACRO-GIGANTISM SYNDROME.

A new cause of childhood-onset gigantism due to excessive growth hormone secretion.

Catherine S Choong MBBS MD, Adrian F Daly MB BCh PhD, Andrew Cotterill MD, Prashant Chittiboina MD, MPH, Albert Beckers MD PhD & Constantine A Stratakis MD DSc.

Discovery:

Pituitary gigantism is a very rare growth disorder that is caused by excessive secretion of growth hormone, usually by a pituitary tumour, starting in childhood and adolescence. The cause of pituitary gigantism is often unknown, but genetic factors play an important role.

In December 2014, a collaboration lead by the research groups of Dr Constantine Stratakis at the National Institutes of Health and Dr Albert Beckers at the Centre Hospitalier Universitaire de Liege, University of Liege, Belgium described a new disorder called X-linked acrogigantism (X-LAG) syndrome. This disorder leads to dramatic growth hormone (GH) induced overgrowth beginning in infancy. They discovered that X-LAG syndrome is due to a microduplication (extra copy) of a region of chromosome Xq26.3 (MIM#300942). This microduplication includes a gene for the orphan G protein-coupled receptor (GPCR), GPR101, which regulates growth by a mechanism that is only just being explored. Importantly X-LAG syndrome can occur both in families as a cause of familial isolated pituitary adenomas (FIPA) and as isolated cases in families with normal growth.

They published this important advance in the understanding of the cause for gigantism in the New England Journal of Medicine (Trivellin et al, 2014). In this and other recent reports (Beckers et al, 2015; Rostomyan et al, 2015), they describe the clinical and pathological characteristics of this newly recognised syndrome in 18 patients worldwide. The unusually early onset of disease that characterizes X-LAG syndrome suggests strongly that this condition might explain many of the most severe cases of gigantism in history (Beckers et al, 2015).

The primary genetic change in patients with X-LAG was detected by a method called array comparative genomic hybridization (aCGH) which utilizes DNA extracted from patients' white blood cells. This technique compares the genetic material of an individual with a reference DNA and can identify increased numbers of genetic regions (duplications) or losses of genetic material (deletions) as compared with normal. The change identified in patients with X-LAG syndrome was a small microduplication on the long arm of the X chromosome (shown in Figure 1); the X chromosome is one of the two sex chromosomes in humans (typically females have two X chromosomes, males have one X and one Y).

The microduplication involved a region that has never been previously recognised as being important in growth disorders. It contains a gene called GPR101, and this extra copy of this gene in X-LAG syndrome appears to have a major disruptive effect on normal growth hormone secretion by the pituitary. This leads to overgrowth of the cells in the pituitary gland that produce GH and another hormone prolactin; this overgrowth (hyperplasia) eventually becomes a pituitary tumour called an adenoma. As the function of GPR101 is almost completely unknown, this discovery has opened a new chapter in our understanding of how growth is regulated.

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IPSEN Innovation for patient care

Clinical Features:

X-LAG syndrome has a very specific presentation. This has been described in a group of 18 patients with the condition. The majority of patients are female and from normal-height families but two families with X-LAG syndrome have been described. Patients are usually born following uncomplicated pregnancies and are generally of normal size at birth. Sometime in the first year of life X-LAG syndrome patients begin to show increased growth in both height/length and weight. This usually occurs by about 12 months of age, but it can be later and many patients are diagnosed between the ages of 3 and 4 years (as shown in Figure 2). Parents report rapid growth, accelerated changes in clothing and shoe size and in some cases this is accompanied by increased appetite and food seeking behaviour (Beckers et al, 2015). In some patients, the insulin level is increased and there is evidence of insulin resistance although none described so far have had diabetes. Some patients had headache and visual changes (Beckers et al, 2015).

The hormonal changes consist primarily of very high levels of growth hormone (GH) and insulin-like growth factor type 1 (IGF-1). The growth hormone levels do not suppress during an oral glucose tolerance test. In most patients prolactin levels are also increased (some markedly so), but none had developed any breast discharge (galactorrhea).

Diagnostic imaging showed pituitary tumours or enlargement that in nearly all cases were larger than 1 cm in diameter (macroadenomas) and most were much larger than this. These tumour sizes are notable when one considers the very young age of the X-LAG syndrome patients at diagnosis (Figure 3). Histopathology of resected tissue usually demonstrates mixed pituitary adenomas with cells positive for growth hormone and prolactin. Some cases have only overgrowth or hyperplasia of these pituitary cells and in other cases both adenoma and hyperplasia coexist.

Therapeutic Options:

Management of this condition is challenging. If neurosurgery occurs at an early stage, it may be curative in some younger patients (i.e. halting vertical growth before permanent adult gigantism can occur). Where a pituitary tumour is distinct and visible, the surgeons' goal is to remove the tumour while leaving the normal pituitary gland intact. In many instances, however, distinct pituitary tumours are not visible and the whole gland appears affected. In those cases, and in cases where the initial tumour removal was not successful in controlling the concentrations of hormones associated with growth (GH & IGF-1), a more radical surgery is considered. This involves surgical removal of the entire pituitary gland (complete hypophysectomy), with many patients requiring a fat graft from the abdomen and a temporary lumbar drain to help prevent leakage of cerebrospinal fluid (CSF).

In other circumstances, medical therapy is warranted. Dopamine agonists such as cabergoline may suppress prolactin secretion but does not markedly affect GH levels or tumour volume alone. Somatostatin analogues do not seem to have a potent effect on growth hormone either when administered prior to or after surgery when there is some remnant tumour tissue. Pegvisomant, a GH receptor antagonist, has been used in some of these patients with good responses in terms of slowing growth and reducing IGF-1 concentrations over the medium term. It is not yet clear how effective or safe this medication is in the longer term and what is the optimal dose for children. In the cohort described by Beckers and colleagues, none of the children receiving pegvisomant had experienced tumour expansion and re-growth of tumour post-surgical resection has not been seen. However even a small residual piece of tumour tissue in X-LAG syndrome can secrete enough growth hormone to require medical therapy for decades. The poor response to octreotide/lanreotide in this cohort is significant (Beckers et al, 2015). While it is too early to be categorical, it is plausible that pegvisomant may be the more efficacious option and could be considered early in medical treatment of this condition. Some patients may require repeated surgery and or radiotherapy. Multiple pituitary hormone deficiency is frequent following therapy particularly in those cured by radical surgery alone, and paradoxically, GH therapy may be needed for normal growth to adult height after surgical cure during childhood.

Perspective:

Mutations in other genes including *AIP, MEN1, PRKAR1A, GNAS1* are known to cause gigantism. Recently Dr Beckers' group published findings from the first comprehensive study of patients with pituitary gigantism (Rostomyan et al, 2015). Of the patients studied, 46% had genetic causes or inherited syndromes. This indicates that a genetic cause remains to be found for more than half of the cases of pituitary gigantism. Earlier diagnosis and control of excessive growth hormone resulted in lower final height, which were closer to the population norms, hence improved awareness of gigantism and quicker referral for diagnosis and treatment are important.

Xq26.3 duplications causing X-LAG syndrome remain rare and predominantly affect girls whose symptoms begin early in childhood. It usually occurs sporadically but it is important to recognise that these microduplications can be inherited. A better understanding and more comprehensive data regarding response to treatment will be helpful toward guiding therapy for future patients with this complex condition. The discovery of this new condition highlights the benefits of international collaboration, and the involvement and interest of families and patients including those from Australasia who provide a tremendous contribution toward clinical and research studies of this rare condition.

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Surgical Neurology Branch, National Institute of Neurological Diseases and Stroke, Bethesda, USA (Chittiboina, P) ; Endocrinology and Genetics, National Institute of Health, Bethesda, USA (Stratakis, CA)

References:

Beckers A, Lodish MB, Trivellin G, Rostomyan L, Lee M, Faucz FR, Yuan B, Choong CS, et al (2015) X-linked acrogigantism syndrome: clinical profile and therapeutic responses. *Endocr Relat Cancer*. 2015 22:353-67. doi: 10.1530/ERC-15-0038

Rostomyan L, Daly AF, Petrossians P, Natchev E, Lila AR, Lecoq AL, Lecumberri Santamaria B, et al (2015) Clinical and genetic characterization of pituitary gigantism: an international study in 208 patients. *Endocr Relat Cancer*. 2015 Jul 17. doi: 10.1530/ERC-15-0320

Trivellin G, Daly AF, Faucz FR, Yuan B, Rostomyan L, Larco DO, Schernthaner-Reiter MH et al, (2014) Gigantism and acromegaly due to Xq26 microduplications and GPR101 mutation. *N Engl J Med*. 2014 371:2363-74. doi: 10.1056/NEJMoa1408028.

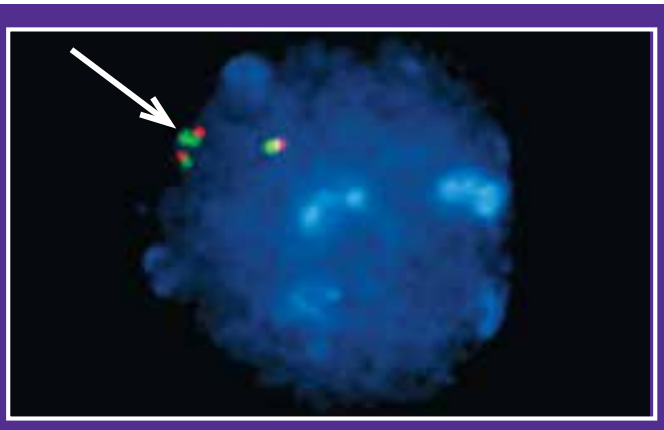


Figure 1: Fluorescent in situ hybridisation (FISH) image of an interphase nucleus from a female patient with X-LAG syndrome due to a chromosome Xq26.3 micro-duplication. On one of the X chromosomes (arrow), there are two copies for genes in the duplicated region (green probe *(ARHGEF6)* and the red probe *(GPR101)*). On the other X chromosome there is a normal signal of one copy for both the green and red probes. Image courtesy of Drs Daly and Beckers.

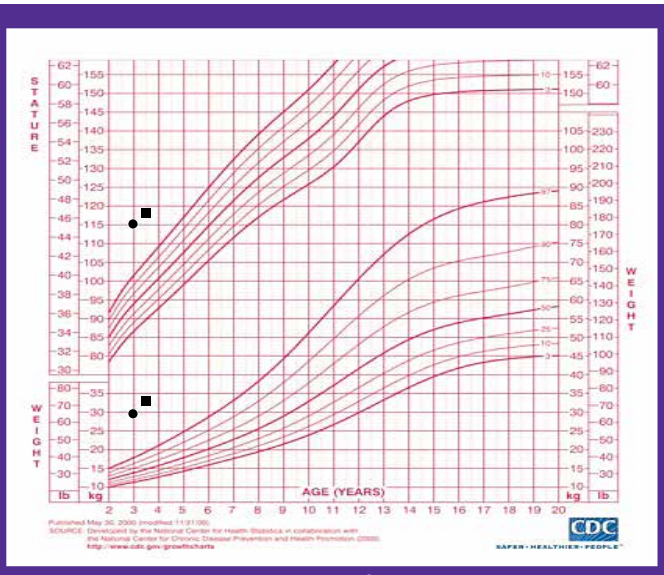


Figure 2: The growth chart for a three-year-old girl demonstrating her height and weight at initial presentation for endocrine assessment (circles), and just before transphenoidal pituitary surgery (squares). Her pituitary tumour is shown in figure 3.

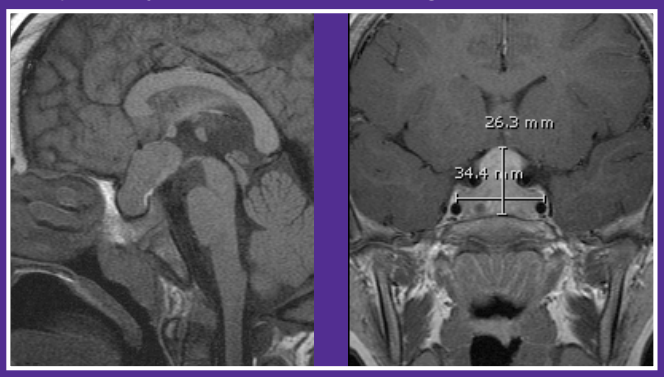


Figure 3: Magnetic Resonance Images of her macroadenoma arising out of an expanded pituitary fossa with significant suprasellar component. The sagittal view is presented in the left panel and the coronal view the right panel. Diagnostic images are reproduced with parental permission.

Patients and families wishing to participate in research related to the genetic causes and treatment of gigantism are invited to contact the Australian Pituitary Foundation at the following address: support@pituitary.asn.au

Patient Story:

"Your daughter has a very rare condition known as pituitary gigantism" - By Toni

At 7 years old, Claire was 157cm tall, and although I had my concerns over the years, it was put to the side because both Richard and I are tall as well.

The events leading up to this statement had started a few weeks before. I was talking to a friend about Claire's unique running groove and she pointed out her tight leg muscles. I tried to make an appointment with a physio but due to Claire's age and height, they requested a paediatrician's ok first. We then saw our GP for a referral and some blood tests to accompany it. We were told the results showed excessive growth hormone (GH) and our referral was changed to an endocrinologist who ordered a MRI of Claire's head.

The MRI showed a 2cm benign pituitary tumour and the endocrinologist explained how this tumour was the reason behind some of Claire's quirks - tall, big feet, gappie teeth, tight muscles, etc. I have to confess at this stage, I had no idea about what a pituitary gland was or where it was even located. And, as you can imagine, google searches are not kind to giants.

Google was also my friend, there was a strong acromegaly community (excess GH in adults) and I scrolled through endless forums trying to find more giants. I found 3 mothers of boys with the condition online myself (Facebook, Twitter and gofundme) and after being referred to join the APF, the APF connected us with a family in Melbourne whose daughter was diagnosed a year earlier. I will never be able

to truly show these families how much I appreciated their help and support in those early days. What surprised me most was, as parents we were united in finding answers, however every single one of our children had their own unique situation and nothing was black and white.

We were then referred to a paediatric endocrinologist, Dr Andrew Cotterill, at the Mater Children's Hospital in Brisbane and were admitted the next day. We started extensive ongoing tests (24 hour blood work, OGTs, DNA testing, MRIs, CTs/Xrays, Vision Field Tests, ECG/echo, etc) and 5 months of medical therapy via somatostatin analogue injections. The aim was to see both Growth Hormone and vision improve, and be able to delay surgery until Claire was older.

In November 2014, it was clear the medication did not have the desired effect and that we could no longer delay surgery. We returned home with this news and our return trip to the hospital was delayed because of the G20 summit interruption in the immediate precinct. We were all pretty down when we next visited Dr Cotterill, uncertain of what the future held. Then BOOM! Dr Cotterill advised we'd been accepted into a research protocol (including treatment) on pituitary tumours at the National Institutes of Health in Washington DC, USA.

It was a very surreal situation - my 7yo girl is a giant, it is very rare (only 100 cases diagnosed in the USA to date), typically once in a lifetime experience for most hospitals and there happens to be a research protocol in the States that can help you.

7 weeks later we boarded a Qantas jet and headed to Washington DC to join Dr Stratakis and Dr Lodish in their research. My main job was to make sure Claire didn't get a cold which could delay surgery - a tricky task considering it was winter in DC and snowing! The hospital was amazing (more people in white coats than patients). The quality of care was remarkable, as was the on-site "Children's Inn" that provided accommodation for the days we didn't need to be on the ward. A lot of the tests we'd already done at the Mater were repeated (plus some), and surgery was scheduled for the 20th January.

The medical team shared with us the genetics behind Claire's specific form of gigantism and the possibility that Claire may not have a tumour, but rather pituitary hyperplasia. During surgery it was confirmed to be hyperplasia and her whole pituitary gland was removed. I'm pleased to share it's now 6 months later and it appears to have worked, as growth hormone is barely registering. Although our cure was at the expense of panhypopituitarism and full hormone replacement, we're going to be ok - it's manageable. Also Claire's contribution to research and their understanding of growth hormone, will hopefully one day also help those with growth deficiencies.

We're back to the National Institutes of Health in Washington DC in December for follow-up review and then our next challenge will be trying to get growth hormone under the PBS in Australia. It will resolve a number of metabolic issues for Claire, however, Claire's height is going to cause concerns with the application. The irony isn't lost on me that I was once desperate trying to STOP GH and now, I'm focused on trying to GET GH!

Our new normal has made us stronger and more appreciative of the blessings in daily life. We were lucky and I truly hope that every parent of a sick child is also given such opportunities. While we were in the National Institutes of Health, we became friendly with a family from Iran whose daughter was being treated for a rare blood disease. We struggled to understand each other, but in our goodbyes, the father best summed up our experience "our talk is different, but our goals are the same". Thank you to Dr Cotterill for his (ongoing) outstanding care and compassion (we are forever grateful) and to the research team at the NIH/NICHD, who are making important discoveries that improve health and save lives, including Claire (extra thanks to Dr Stratakis, Dr Lodish, Dr Chittiboina and Dr Lysikatos-Lyssikatos).

I'd also like to thank the APF who supported us from the very start. From coming to terms with understanding our gentle giant (phone calls, connections, resources, Facebook group, etc) through to our new life on full hormone replacement. The APF had been amazing and I strongly encourage members to get involved in their education and social events or their Facebook group.

At a recent Qld Branch event Claire made a friend, Elizabeth, who is 9 years old and also has panhypopituitarism (from birth). Elizabeth is a beautiful role model for Claire to reaffirm that our new normal is "A-OK" (and for me, I met some adult members who were also fine living with PHP). Claire and Elizabeth's friendship also provided both families an opportunity to compare the two extremes - both at a similar age - one with excessive GH for the first 7 years, the other with no GH from birth and on GH replacement. This is the beginning of a life-long friendship - thank you APF.

WHAT WE'RE DOING – NATIONAL & STATE REPORTS

A Message from the Chairperson

The Foundation has been extremely busy putting together quality information to GPs and educational events for patients, which are demonstrated in this newsletter. 2 more GP events are organised for this year, with 2 patient education sessions in Bendigo, Victoria.

Our AGM is scheduled for Sunday, 18th October. A small number of Directors hope to retire to make space for "new blood" to take the Foundation forward. This has been necessitated due to longevity on the board and personal health and life challenges.

Joining our board will be an immensely rewarding experience. Getting involved can pay huge dividends as you watch and contribute to the building of something special. APF can offer a greater sense of achievement.

We are particularly looking for those with professional skills in marketing, fundraising and advocacy who can share their industry skills. People with personal connections to pituitary would be ideal, (even family or close associates) however this is not a fixed requisite. Nomination forms will be distributed to voting members soon.

Noel Hickey

QLD

Social News:

Ever wanted to do the CityCat ride up and down the river? Now's your chance!

We plan to have a BBQ at Gyatt Park, St. Lucia which is a very shady and uncrowded unique little park where we can relax and the kids can play. After lunch we'll board the CityCat for a return trip up and down the Brisbane River to see the sights, with a stop at one of the terminals for an ice-cream.

Plan is a Saturday in September, please look over the invite when it arrives.

Sue

NSW

Social News:

Best wishes to everyone in NSW. I've been busy sourcing new employment so to date have not arranged a social gathering, however we will all get together before Christmas.

Daniel

WA

Social News:

It was great to see the usual crowd at dinner prior to the education events the following morning. Unfortunately I didn't get a quick enough photo before everyone started to leave. Thanks to everyone who attended.

Seminar News:

What a great day on Saturday 1st August, where we held a combined adult/paediatric/adolescent education day, with doctors and nurses from Sir Charles Gairdner Hospital and Princess Margaret Children's Hospital.

Adult Session:

A number of patients and nurses attended the morning session which was great. The topics included information on the adrenal and thyroid glands, explaining their function in the healthy body, what can go wrong and how to manage the situation. Thank you once again to Dr David Henley and Dr Ee Munn Lim who have presented for us on a number of occasions. I was particularly chuffed to have my own doctor, Dr Joey Kay present on Prolactinoma management which proved to be very interesting. Thanks to all the nurses who attended.

Dr David Henley, nurse Alicia Linn and Pete Marsh.

Dr Ee Munn Lim and Dr Joey Kay.

The usual group was there along with some new people

Paediatric Session:

Nurse Maree Grant, who some of you would be familiar with, assisted us to connect with doctors at Princess Margaret Children's Hospital which transpired into a great afternoon. A small number of parents attended, a few nurses and a visiting Endocrinologist. Dr Catherine Choong gave an insight into puberty and Dr Aris Siafarikas spoke about bone health. These presentations go hand in hand in the understanding of growth. Dr Kiranjit Joshi and Dr Tarini Chetty, Endocrine fellows, lectured on Adrenal Crisis & Hydrocortisone injection practice. Some very relevant questions were answered on conclusion of the afternoon.

Nurse Maree Grant, Dr Catherine Choong, Dr Aris Siafarikas

Dr Kiranjit Joshi and Dr Tarini Chetty

We're pleased to say that a wonderful donation from Mrs. Garis afforded us to film the events and we hope to have them uploaded to the members area of the website soon.

Pete

APF MATTERS - NOTICES AND NEWS

Centrelink Presentation:

Professor Kenneth Ho accepted an invitation from APF to attend a Centrelink Conference in Brisbane to assist staff in the understanding of the disabilities of patients with pituitary disease.

85 health and allied health professionals attended, and APF was impressed with the amount of general knowledge they knew of these rare and poorly understood diseases.

To further their knowledge we distributed a number of our booklets and promoted access to the Health Professional Portal of our website for their further interest. We also took the opportunity of promoting APF support and services we provide to patients and health professionals.

Professor Ho has been an ongoing supporter of the APF since its inception, and we thank him for continually giving his time.

GPCE:

Sue & Pete attended the General Practitioner Conference & Exhibition in Perth on 25th & 26th July.

Dr David Hurley presenting to a room full of GPs!

Dr David Hurley and WA Representative Pete Marsh.

Dr David Hurley presented for us on both days. Once again we had a full room of attendees on the Saturday and on the Sunday a good number attended.

Perth was a smaller audience, though we found the interest in visiting our stand better than the Sydney GPCE. So many GPs and practice nurses saw us there, and Pete loved sharing his experience of living with and treating Acromegaly, including his successful treatment, by clinical trial, with Pegvisomant which is currently not available in Australia.

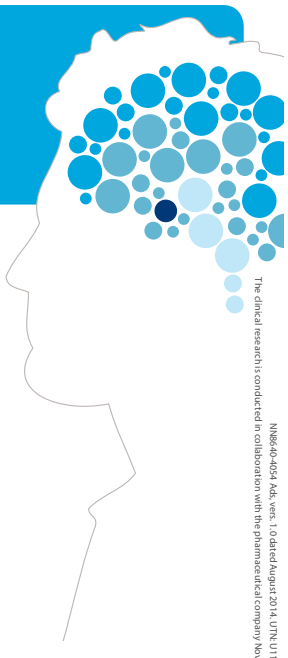
Some-one asked us how we measure the level of success of attendance at these conferences. We do not sell merchandise, nor do we sell services – there is no financial gain to us. BUT, there is a huge gain in the community when GPs have a greater awareness of pituitary conditions. APF was so excited to receive a phone call from a GP in Perth a week later, who stated he had just diagnosed a patient with Acromegaly, and where was he to go from there. An Endocrinologist of course!!! Besides from pituitary tumours Dr Hurley effectively delivered information on hormone deficiencies and treatments, which we are sure will assist GPs in managing their existing and future patients, including children.

Pituitary Awareness Week

Pete was very busy in WA. He attended the GPCE on that weekend, manned a pituitary awareness stall all week, visited clinicians and nurses at various Perth hospitals and hosted a patient education event the following weekend! Phew! APF would like to sincerely thank Pete and long-time stalwart of the Foundation, Lana for manning the awareness stall that week. It proved to be successful with Pete and Lana speaking to various people with pituitary conditions. Lana was delighted to be shown through the radiation oncology unit at at Sir Charles Gairdner Hospital with Dr. Brendan McKernan.

Nicholas Wolf from GPCE visiting the APF stand

Do you have growth hormone deficiency? REAL 1



Consider Volunteering

If you have growth hormone deficiency and have not received any growth hormone treatment, or have not received any growth hormone treatment within the last 6 months (180 days), you may be eligible to take part in this clinical research trial.

You may qualify if you:

- Are between 23 and 79 years of age, both inclusive
- Have a confirmed diagnosis of growth hormone deficiency with either adult or childhood onset
- Have not received treatment with growth hormone or other growth factors within the last 6 months (180 days)

In the trial, a once weekly growth hormone treatment is compared to once daily growth hormone treatment and to placebo (inactive drug).

If you are interested and would like to have more information, please contact:

Royal Melbourne Hospital, VIC: Research Manager (03) 9342 7344
Eastern Clinical Research Unit, VIC: REAL 1 Research Nurse (03) 9094 9520
Keogh Institute for Medical Research, WA: REAL 1 Study Coordinator (08) 9346 2475
Royal North Shore Hospital, NSW: REAL 1 Study Coordinator (02) 9463 1864
Blacktown Hospital, NSW: REAL 1 Study Team (02) 9851 6073

REAL 1
safety and efficacy of once-weekly reversible albumin binding growth hormone in AGHD

The clinical research is conducted in collaboration with the pharmaceutical company Novo Nordisk A/S

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Next Newsletter

If you would like to contribute, please send your submission by email (membership@pituitary.asn.au) or fax it to 07 3376 2896.
Photos and graphics are always very welcome.
The next edition is planned for November 2015
Deadline: 15 November 2015

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LINKING PEOPLE WITH INFORMATION

Making a donation

Australian Pituitary Foundation Ltd is the only national not-for-profit organisation dedicated to supporting and advocating for patients and families living with the effects of pituitary disease and disorders. You can help to sustain our services by making a donation. Please fill out the form below or go to www.pituitary.asn.au to make your gift online.

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