PLACEBO-CONTROLLED TRIAL ON THE EFFICACY OF GROWTH HORMONE REPLACEMENT THERAPY IN PATIENTS WITH GROWTH HORMONE DEFICIENCY AFTER TRAUMATIC BRAIN INJURY

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON31323

Source
ToetsingOnline

Brief title
A6281289

Condition

- Hypothalamus and pituitary gland disorders

Synonym
growth hormone deficiency

Research involving

Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Pfizer

Intervention

Keyword: growth hormone deficiency, placebo-controlled, traumatic brain injury (TBI)

Outcome measures

Primary outcome

The primary endpoint is the change from baseline in the CogState* composite

score at Week 36.

Secondary outcome

• Change from baseline in CogState* composite score at Week 12 and 24.

• Change from baseline in lean body mass and fat mass (kg) as measured by Dual

Energy X-ray Absorptiometry (DXA) at Week 36.

• Change from baseline in neurological outcome as assessed by the Extended

Glasgow-Outcome-Scale (GOS-E) at Week 36.

• Change from baseline in quality of life using SF-36 Health Survey at Week 36.

• Change from baseline in Assessment of Growth Hormone Deficiency in Adults

(AGHDA) questionnaires at Week 36.

Study description

Background summary

Genotropin® is somatropin (in injectible form) and is able to replace the human growth hormone because it is a copy of the natural growth hormone made by the body*s pituitary gland. The only difference is Genotropin® is a man-made

product. Genotropin® is approved for the treatment in adults for growth hormone deficiency and it has been used in over 53,000 patients worldwide and this drug has been studied for over 10 years.

Study objective

The present study will investigate the benefits of Genotropin® in patients suffering from severe GH deficiency after TBI and will focus on the potential effects on cognitive function

The primary objective of this study is to establish the effects of Growth Hormone (GH) replacement in patients with severe GH deficiency after Traumatic Brain Injury (TBI) on cognitive function.

Study design

This study will enroll approximately 120 patients and will comprise of 2 phases, a screening phase and a 36-week multicenter, double-blind, placebo-controlled phase:

1. The screening phase will be up to 1 month on subjects who have suffered a TBI and have proven or suspected GH deficiency (after testing).

2. The double-blind treatment phase will be 36 weeks during which eligible subjects will receive placebo or recombinant growth hormone in a 1:1 randomization ratio.

Intervention

Subjects randomized to receive treatment with Genotropin® (somatropin) will be initiated at a dosage of 0.2 mg/day s.c. in men and 0.3 mg/day s.c. in women. Dose adaptation will take place monthly until the subject has stabilized in the upper half of the normal range.

Study burden and risks

Besides the treatment patients will undergo:
-pulse and blood pressure (5x)
-Waist Circumference (2x)
-pregnancy test (1x)
-blood draw (4x)
-body composition DXA machine (2x)
-cognitive function test (5x)
-2 questionnaires (2x), 1 questionnaire (3x)

Some of the side effects are:

• Fluid retention - causing swelling.
• Stiffness of the extremities
• Myalgia (muscle pain/aches)
• Arthralgia (Severe Joint pain)
• Paraesthesia (skin sensation, burning, prickling, itching, tingling with no apparent physical cause.)
These side effects are common and can occur in 1 to 10% of patients, and:
• Diabetes type II
• Headache (due to benign intracranial hypertension)
These side effects are rare and occur only in 0.01% of patients.

Redness, swelling and bruising might develop on the location of injection.

Contacts

Public
Pfizer

Rivium Westlaan 142
2909 LD Capelle a/d IJssel
Nederland
Scientific
Pfizer

Rivium Westlaan 142
2909 LD Capelle a/d IJssel
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Be at least 18 years of age and at the age of legal consent, and no older than 55 years of age (men and women).;2)Have had a previous TBI (more than 1 year and less than 10 years) prior to the screening visit.;3) Have proven severe GH deficiency as diagnosed by dynamic testing within the last 6 months.

Exclusion criteria

1) Has any current malignancy except:
a. Those >5 years ago without recurrence.
b. Excised basal cell carcinoma or squamous cell cancer.
2) History of cranial irradiation.
3) Growth hormone replacement therapy in the last 12 months.
4) History of hypothalamic / pituitary disease which was diagnosed prior to TBI.
5) History of dementia unrelated to TBI.
6) History of benign intracranial hypertension.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2008
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Genotropin
Generic name:	somatropin (growth hormone)
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-08-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-12-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-08-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-11-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-003586-41-NL
CCMO	NL19113.078.07