Changes in thoracolumbar kyphosis in achondroplasts

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Long term follow up is lacking in this database. A follow up study in which patients in the database are invited to a follow up exam and imaging would be a much more complete picture of the development of TLK in achondroplasten.

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON41492

Source
ToetsingOnline

Brief title
TLK in achondroplasia

Condition

- Congenital and hereditary disorders NEC
- Musculoskeletal and connective tissue disorders congenital
- Spinal cord and nerve root disorders

Synonym
dwarfism, little people

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: achondroplasia, bracing, thoracolumbar kyphosis

Outcome measures

Primary outcome

A lateral X ray image will be made of the entire spine. TLK is measured by the

Cobbs angle.

Secondary outcome

A lateral X ray image will be made of the entrie spine. TLK is measured by the

Cobbs angle and the sagittal balance and the pelvic incidence are calculated.

Questionnaires will be collected:

VAS back pain

EQ5D

DS14 of the accompanying parent

MDI

Cooper lower extremities

VAS health

Study description

Background summary

Achondroplasia is characterized by a defect in the cartilage rebuilding. As a result, not only shortening of the limbs, but also the anatomy of the spinal column is abnormal. This predisposes to all sorts of problems. One of these problems is the frequent occurrence of a thoracolumbar kyphosis (TLK) which can lead to compression of spinal cord and / or cauda equina. This can lead to motor and sensory disturbances in the legs and micturition and pain. This research is focused on this kyfosis identification and optimal treatment strategy for ensuring the prevention of progression of kyphosis.

The transition from the thoracolumbar spine normally does not exhibit a kyphotic angle. In children with achondroplasia, most seem to be born with a kyphotic angle of the thoracolumbar transition. A retrospective study that we conducted using a database of 105 achondroplastic children of the orthopedic department of the UMCU showed that 68% of the children had TLK.
The achondroplast children who were reported to the orthopedic department were checked for the presence of these TLK and a treatment protocol was instituted. This protocol consisted of avoiding the upright position until the child sits by itself. Furthermore, the kyphosis was frequently checked and a redressing corset was applied if the kyphosis angle exceeded 30 degrees. Retrospective analysis of the database showed that in about half of the children TLK disappeared (with or without therapy) and that in the other half of patients TLK deteriorated and that in half of those patients bracing or surgery was required.

Study objective

Long term follow up is lacking in this database. A follow up study in which patients in the database are invited to a follow up exam and imaging would be a much more complete picture of the development of TLK in achondroplasten.

Study design

In the LUMC adult achondroplasts with symptoms of spinal canal narrowing in the high lumbar and low thoracic transition are frequently seen. TLK often occurs in these patients. This study will place TLK in a context in which anatomy of the spine and in particular sagittal balance and pelvic incidence of achondroplast, are further studied. It is suspected that sagittal balance and pelvic incidence (terms to the anatomy and distribution of forces in the spine in size and number to indicate) the achondroplast correlated with symptom pattern. These parameters would even have prognostic value.

question:
How does TLK develop as the child gets older?
Is there a correlation between clinical symptoms and TLK?
Does progression of TLK exists in the adult population?
Is the presence of TLK correlated with an increased number of surgical interventions on the spine?
Is sagittal balance affected by the thoracolumbar kyphosis?
Is pelvic incidence influenced by the thoracolumbar kyphosis?

Study burden and risks

There will be an x-ray. This gives a low radiation dose

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

achondroplasia. Patients have been evaluated before. They were treated on the orthopaedic or neurosurgical department and frequently they are still visiting the outpatient clinic.

Exclusion criteria

n.a.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-08-2015
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-11-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	27-11-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	09-09-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL43032.058.13