Positron Emission Tomography as a diagnostic tool in Unilateral Condylar Hyperplasia and comparison with bone scintigraphy, including SPECT

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Finding answers to the folowing questions:Does 18 fluoride PET research have the potential to make a better differentiation between an active and inactive condyle in comparison to bone scintigraphy including SPECT in patients with a Unilateral...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30174

Source
ToetsingOnline

Brief title
PET and Unilateral Condylar Hyperplasia

Condition

- Other condition

Synonym
growth of the temporo-mandibular joint, Unilateral Condylar Hyperplasia

Health condition

Temporo-Mandibulaire Gewricht

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Positron Emission Tomography, Single Photon Emission Tomography, Temporo-Mandibular Joint, Unilateral Condylar Hyperplasia

Outcome measures

Primary outcome

Difference of bone activity between the hyperplastic and contralateral condyle.

The results of planar and SPECT research will be compared to PET research.

Secondary outcome

Difference in vascularisation between the hyperplastic and contralateral

condyle. We'll assess if there is a higher bloodflow in the hyperplastic

condyle in comparison to the contralateral condyle.

Study description

Background summary

In Unilateral Condylar Hyperplasia (UCH), an asymmetrical development of the mandible can be noticed, based on a unilateral persistant or renewed growth of the condyle.
Before (surgical) correction of a mandibular asymmetry, it is mandatory to assess whether or not the growth centre of the condyle is still active, to prevent unnecessary surgery to the joint or on the other hand, progression of the asymmetry after correction.
Nowadays, progression of the asymmetry is assesed by clinical and radiological follow up, planar scintigraphy and SPECT research.
The aim of the PET study is to determine whether or not a better differentiation between patients with or without asymmetrical bone activity in the condyles can be made. Kwantification of 18F- uptake seems to be superior to

the semi-kwantitative methods, used in bone scintigraphy including SPECT.
In regard to the pathogenesis, which is still unknown, vascularisation of the condyle regions will be measured.

Study objective

Finding answers to the folowing questions:

Does 18 fluoride PET research have the potential to make a better differentiation between an active and inactive condyle in comparison to bone scintigraphy including SPECT in patients with a Unilateral Condylar Hyperplasia (UCH)?

Can a higher vascularisation be noticed in a condyle with persistent growth in comparison to the contralateral side? This in regard to the unknown pathogenesis.

Study design

Observational research

Study burden and risks

Burden: 1 artery and 1 venous line will be inserted in the lower arm. Patients can't move during the PET scanning

Radiation dose per scan: 3 milliSievert
The radiation dose of a Dutch citizen based on radiation from the universe during 1 year, is 2-2,5 mSv. The radiation dose due to this study seems to be acceptable

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
1081 HV Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
1081 HV Amsterdam

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

suspicion of progressive mandibulair asymmetry and clinical suspicion of an unilateral condylar hyperplasia.
Age 18-40 years

Exclusion criteria

Pregnancy
The inability of lying on the back during 1 hour
Nuclear or radiologic research in the year prior to this study, with a yeardose of more than 10 mSv

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	6
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL11893.029.06