

Single-photon emission computed tomography/computed tomography in patients with a suspected Unilateral Condylar Hyperactivity.

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To assess the diagnostic performance (sensitivity, specificity, ROC curve) of the bone SPECT/CT scans. To assess the intra- and interobserver variability of SPECT/CT in patients suspected of having UCH.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON39064

Source

ToetsingOnline

Brief title

SPECT-CT in patients with UCH

Condition

- Bone disorders (excl congenital and fractures)

Synonym

condylar hyperplasia

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Geen extra geldstromen

Intervention

Keyword: condylar, hyperactivity, hyperplasia, SPECT-CT

Outcome measures

Primary outcome

The primary endpoint is the sensitivity and specificity of the bone SPECT/CT scan compared to the sensitivity and specificity of the SPECT scan in patients with a suspected UCH. To provide a receiver operating characteristics (ROC) curve in order to select the optimal diagnostic method (SPECT/SPECT-CT).

Secondary outcome

The second endpoint of this study is the inter-observer and intra-observer agreement for the SPECT/CT scanning in patients with a suspected UCH

Study description

Background summary

SPECT/CT is a hybrid imaging technique which combines anatomical computed tomography (CT) and functional scintigraphic imaging. The fusion of form (CT) and function (SPECT) greatly improves the diagnostic information obtainable from using either technique alone. The hypothesis of this study is that SPECT/CT imaging will improve the diagnostic accuracy for unilateral condylar hyperactivity over conventional SPECT imaging.

Study objective

To assess the diagnostic performance (sensitivity, specificity, ROC curve) of the bone SPECT/CT scans. To assess the intra- and interobserver variability of SPECT/CT in patients suspected of having UCH.

Study design

Prospective clinical diagnostic study. Patient with a mandibular asymmetry

suspected to have UCH receive a bone SPECT/CT to determine if there is an active growing condyle. The original SPECT data can be extracted out of the SPECT/CT images. The results of clinical follow-up or surgery and histology of the specimen are compared to the initial SPECT and SPECT/CT results.

Study burden and risks

this study adds a low dose CT to the SPECT scan which increases the radiation dose to the patient. In the case of UCH it is appropriate to limit the CT field of view to the condylar region to minimize the additional radiation. The outcome of this study is of great importance for the future diagnostic and treatment strategy for patients with a mandibular asymmetry. SPECT/CT can be used to optimize the treatment strategy and to prevent unnecessary surgical procedures or unnecessary clinical progression of the disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

-progressive facial asymmetry with mandible involvement

Exclusion criteria

-facial asymmetry suspected to be based on a non-UCH cause
-apparent temporomandibular joint disorder
-apparent systemic or local bone disease

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2013

Enrollment: 30

Type: Actual

Ethics review

Approved WMO

Date: 29-06-2013

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	NL39426.029.13