Value of multimodality image registration of cone-beam CT and CT in adrenal vein sampling procedures in increasing success rate

Published: 03-04-2013 Last updated: 25-04-2024

To determine the value of multimodality image registration of cone-beam CT (CBCT) and CT in increasing the success rate of adrenal vein sampling procedure compared to procedures without CBCT guidance.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Adrenal gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON40056

Source ToetsingOnline

Brief title Image regsitration in AVS

Condition

Adrenal gland disorders

Synonym

hypersecretion of aldosterone by adrenal gland(s), Primary aldosteronism

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

1 - Value of multimodality image registration of cone-beam CT and CT in adrenal vein ... 13-05-2025

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adrenal vein sampling, cone-beam CT, CT, image registration

Outcome measures

Primary outcome

The main parameter is the success rate of the AVS procedures with and without

multimodality image registration.

Secondary outcome

Other parameters are radiation dose, number of DSA runs used, used volume of

contrast agent, fluoroscopy time, and sampling time

Study description

Background summary

Adrenal vein sampling (AVS) is the gold standard in differentiating between unilateral and bilateral hypersecretion of aldosterone by the adrenal glands. However, it is a complex procedure with high failure rates. Locating and sampling the right adrenal vein is the most difficult part. Using image guidance visualizing the adrenal veins can possibly aid in AVS procedures and increase the success rate.

Study objective

To determine the value of multimodality image registration of cone-beam CT (CBCT) and CT in increasing the success rate of adrenal vein sampling procedure compared to procedures without CBCT guidance.

Study design

Open randomized controlled trial to compare AVS procedures with and without multimodality image registration.

Study burden and risks

The CT scan and AVS procedure involve X-ray imaging. Both are performed as clinical care and conform clinical practice. The study group will receive an additional CBCT scan, however, we expect the total radiation dose of the procedure not to increase compared to the standard protocol. Therefore, we assume that there will be no additional risk to the patients participating in this study compared to the standard clinical care. In case the success rate of the AVS procedures increases with multimodality image registration, the benefit for the total group of patients is a reduction in repeat AVS procedures because of procedure failure and thus overall radiation dose reduction. Other parameters that might be beneficially influenced by multimodality image registration for the total patient group are reduced sampling time and reduction of used contrast volume.

Contacts

Public

Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10 Nijmegen 6525 GA NL **Scientific** Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10 Nijmegen 6525 GA NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

diagnosed with primary hyperaldosteronism and referred for adrenal vein sampling

Exclusion criteria

none

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

...

NL	
Recruitment status:	Recruiting
Start date (anticipated):	21-06-2013
Enrollment:	80
Туре:	Actual

Ethics review

Approved WMO	
Date:	03-04-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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 CCMO **ID** NL41450.091.13