Feasibility of MRI-imaging of the Affinis short shoulder prosthesis

Published: 06-07-2012
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To Establish the usefulness of MRI for assessment of the rotator cuff in patients with an Affinis short prosthesis implanted in the shoulder.

Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38132

Source
ToetsingOnline

Brief title
feasibility of MRI in Affinis short prosthesis

Condition

- Tendon, ligament and cartilage disorders

Synonym
rotator cuff ruptures, tendon leasions in the shoulder

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: bedrijf (leverancier schouderprothese)

Intervention

Keyword: Affinis short, MRI, prosthesis, shoulder

Outcome measures

Primary outcome

Interpretation and value of MR-imaging of the rotator cuff with prosthesis in

situ

Secondary outcome

Interpretation of MR-imaging of condition of the bone stock

Interpretation and usefulness of MR-imaging results in diagnosis of: glenoid

pathology, position of the prosthesis,

loosening of the prosthesis, polyethylene wear and determining if there might

be an infection.

Study description

Background summary

normally a MRI is not a good way to evaluate the rotator cuff after placing a shoulder prosthesis. because of the prosthesis this isn't possible, especially because of the cobalt chroom containment. this prosthesis doesn't contain cobalt chroom, so we think it is possible to get a good clear view on the rotator cuff. so we can have a follow-up and maybe see in the future the moment to place another prosthesis.

Study objective

To Establish the usefulness of MRI for assessment of the rotator cuff in patients with an Affinis short prosthesis implanted in the shoulder.

Study design

All the patients will have received their normal postoperative follow-up. They will have been seen two, six and twelve weeks after the operation. The MRI*s for this diagnostic study will be conducted after six and twelve months, but all the patients that had an MRI scan done pre-operatively with a clear

clinical indication may be included as well.

Study burden and risks

the normal risks of making a MRI,

Specific MRI incompatibility such as severe claustrophobia or patients with pregnancy,implanted electronic devices, such as pacemakers, internal defibrillators, some cochlear implants and nerve stimulators. Patients with
ferromagnetic aneurysm clips in the brain or ferromagnetic objects in critical
places like the eye, brain, lung.

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

only people with an Affinis short shoulder prosthesis will be included

Exclusion criteria

claustrophobia, contra-indication MRI, insufficient knowledge Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2013
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-07-2012
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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
CCMO	NL34779.101.12