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The Delphi Trial I(RCT)2 international randomised clinical trial of rheumatoid craniocervical treatment: an intervention-prognostic trial comparing 'early' surgery with natural history

Submission date
25/01/2005

Recruitment status
No longer recruiting

Registration date
19/04/2005

Overall study status
Completed

Last Edited
03/10/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DAA 04-1-05; NTR474

Study information

Scientific Title
The Delphi Trial I(RCT)2 international randomised clinical trial of rheumatoid craniocervical treatment: an intervention-prognostic trial comparing 'early' surgery with natural history

Acronym
The Delphi I(RCT)2

Study objectives
There is no difference between early surgery and prolonged conservative treatment.

The prevalence of rheumatoid arthritis is 0.8 - 1%. The upper cervical spine shows signs of damage in 17 - 86% of patients with rheumatoid arthritis (RA). Once neurological deficits develop prognosis is poor. Surgery is advocated by most international centres in an early stage to prevent neurological deterioration and radiological progression of abnormalities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Early surgery versus prolonged conservative treatment:
1. Surgical treatment (A) Operation technique: C1C2 screw fixation according to Magerl or Harms with or without wiring techniques
2. Prolonged conservative treatment (B): The treatment of rheumatoid arthritis patients is aimed primarily at rapid reduction of disease activity by disease-modifying anti-rheumatic drugs, thus preventing (progression of) damage, including subluxation, and maintenance/restoration of physical (including neurological) function

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

The primary outcome is the occurrence of a major event:
1. Neurological disability
2. Radiological progression
3. Surgery (B) or resurgery (A)
4. Death (all causes)

Key secondary outcome(s))
1. Ranawat
2. ASIA
3. DAS-28 instrument
4. Visual Analogue Scale (VAS)
5. EuroQol instrument
6. ST-36 instrument
7. Functional X-ray
8. Magnetic resonance imaging (MRI)

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. Rheumatoid arthritis patients
2. Aged 18 to 70
3. Ranawat I and II: no neurological impairment
4. C1-C2 subluxation: anterior atlanto-dental interval (AADI) 5 to 12 mm, posterior atlanto-dental interval (PADI) more than 10 mm
5. C1-C2 subluxation may be reducible as well as irreducible
6. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Ranawat IIIA and IIIB: neurological impairment
2. Severe comorbidity
3. Previous craniocervical operations

4. Klippel Feil syndrome
5. C1-C2 subluxation: AADI less than 5 mm or more than 12 mm or PADI less than 10 mm
6. Magnetic resonance imaging (MRI) incompatibility

Date of first enrolment
01/03/2005

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
United Kingdom

Belgium

Canada

Denmark

France

Germany

Italy

Latvia

Netherlands

Portugal

Spain

Sweden

Switzerland

United States of America

Study participating centre
Albinusdreef 2
Leiden
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Sponsor information

Organisation
Reumafonds (Dutch Rheumatoid Arthritis Foundation) (The Netherlands)

ROR
https://ror.org/05dr3r825

Funder(s)

Funder type
Research organisation

Funder Name
Reumafonds (Dutch Rheumatoid Arthritis Foundation) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol	16/02/2006		Yes	No