

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/10/2018	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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)

Secondary outcome measures

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)

Overall study start date

01/03/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

250

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**

Belgium

Canada

Denmark

France

Germany

Italy

Latvia

Netherlands

Portugal

Spain

Sweden

Switzerland

United Kingdom

United States of America

Study participating centre

Albinusdreef 2

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Reumafonds (Dutch Rheumatoid Arthritis Foundation) (The Netherlands)

Sponsor details

Dr Jan van Breemenstraat 4

Amsterdam

Netherlands

1040 KB

Sponsor type

Research organisation

ROR

<https://ror.org/05dr3r825>

Funder(s)

Funder type

Research organisation

Funder Name

Reumafonds (Dutch Rheumatoid Arthritis Foundation) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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