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Changes in bone density and bone turnover in patients with rheumatoid arthritis treated with rituximab, a B cell depleting antibody

Submission date 28/04/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/06/2010	**Overall study status** Completed	
Last Edited 04/02/2016	**Condition category** Musculoskeletal Diseases	

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
v1.7 08Jun10

Study information

Scientific Title
Changes in bone density and bone turnover in patients with rheumatoid arthritis treated with rituximab, a B cell depleting antibody: A multicentre, open-label, prospective clinical trial with single treatment arm

Acronym
RituxRABone

Study objectives
B cell depletion with rituximab suppresses inflammation and bone turnover in rheumatoid arthritis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committees of Leiden and Utrecht University Medical Centres in the Netherlands and the Research and Development department at The James Cook University Hospital, UK.

Primary study design
Interventional

Study design
Multicentre open label single treatment arm prospective clinical trial

Study type(s)
Treatment

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

Interventions
This is a single treatment arm study involving 2 intravenous infusions of rituximab (1,000 mg /infusion) and methylprednisolone (100 mg/infusion), two weeks apart, as licensed for rheumatoid arthritis. Retreatment will be given if patients do not have low disease activity at 6 months according to standard practice. The duration of follow up is one year following the first infusion.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rituximab, methylprednisolone

Primary outcome(s)
Change in bone mineral density of spine, measured by Dual Energy X-Ray Absorptiometry (DEXA) at baseline and 12 months

Key secondary outcome(s)
1. Changes in bone mineral density of hips and forearms, measured by Dual Energy X-Ray Absorptiometry (DEXA) at baseline and 12 months
2. Changes in biochemical markers of bone turnover
3. Changes in biomarkers of inflammation and autoreactivity
4. Changes in disease activity
5. Number of new fractures
6. Duration of B cell depletion in blood
All other outcomes (2-6) will be measured at baseline, 3, 6, 9, and 12 months using the following tools: Disease Activity Score for 28 Joints (DAS28), a validated and routine clinical assessment; Health Assessment Questionnaire (HAQ) a questionnaire-based investigation; Biomarkers are measured by a range of techniques incl flowcytometry, ELISA.

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Age 18 or older
2. Established diagnosis of rheumatoid arthritis
3. Eligible for treatment with rituximab
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Concurrent bisphosphonate use
2. Poor previous compliance

Date of first enrolment
01/08/2010

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Tees Hospitals NHS Foundation Trust
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Industry

Funder Name
Roche (UK)

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?
Results article	results	01/12/2011		Yes	No