

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 07/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/02/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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.

Study design

Multicentre open label single treatment arm prospective clinical trial

Primary study design

Interventional

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