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Trial in Rheumatoid Arthritis of Lisinopril

Submission date 19/12/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/04/2006	**Overall study status** Completed	
Last Edited 14/06/2017	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cambridge-arthritis.org.uk/tralis.php

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TRALIS001

Study information

Scientific Title
Trial in Rheumatoid Arthritis of Lisinopril

Acronym
TRALIS

Study objectives
That the angiotensin converting enzyme (ACE) inhibitor, lisinopril will:
1. Reduce rheumatoid disease activity
2. Improve vascular correlates of active rheumatoid arthritis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Multicentre Research Ethics Committee, 01/02/2006, ref: 05/MRE04/93

Study design
Randomised double-blind placebo-controlled dual-arm study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.cambridge-arthritis.org.uk/tralis.php?name=TRALIS

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

Interventions
Treatment with lisinopril 20 mg once daily versus placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lisinopril

Primary outcome measure
Rheumatoid disease activity score 28 (DAS28)

Secondary outcome measures
1. Swollen joint count
2. Flow-mediated dilatation (FMD)
3. Aortic pulse wave velocity (PWV)
4. Aortic augmentation index (AIx)
5. High sensitivity C-reactive protein
6. Serum cartilage oligomeric matrix protein (marker of cartilage breakdown)
7. Serum soluble intercellular adhesion molecule (ICAM-1) (marker of endothelial activation)

Overall study start date
23/01/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Age ≥18 years and ≤80 years
2. Diagnosis of rheumatoid arthritis
3. Stable dose of disease-modifying anti-rheumatic drug (DMARD) (conventional or biological) over one month preceding the trial
4. Residual disease activity - disease activity score 28 (DAS28) >3.5
5. Use of adequate contraception in females of child-bearing potential

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Major surgery within six weeks
2. Other systemic inflammatory diseases or inflammatory arthritis (e.g. systemic lupus erythematosus [SLE], scleroderma, vasculitis, spondyloarthropathy, crystal arthropathy)

3. Functional class IV unable to mobilise without assistance from another individual or wheelchair-user
4. Treatment with another investigational agent within four weeks
5. Intra-articular or parenteral corticosteroids within four weeks of screening visit
6. Chronic use of corticosteroid >7.5 mg prednisolone (or equivalent)
7. Variation in dose of corticosteroid <7.5 mg prednisolone (or equivalent) in one month prior to screening visit
8. Current use of ACE inhibitor or angiotensin receptor blocker
9. Allergy to ACE inhibitor or angiotensin receptor blocker
10. Blood pressure (BP) ≤100/60; BP ≥180/100
11. Left ventricular failure
12. Major infective episode requiring hospitalisation or treatment with intravenous (IV) antibiotics within four weeks of screening or oral antibiotics within two weeks prior to screening
13. Current solid organ or haematological malignancy
14. Pregnancy or breastfeeding
15. Renal impairment with estimated creatinine clearance of <50 ml/min
16. Aspartate aminotranferase (AST) and alanine aminotransferase (ALT) AST/ALT >100 IU/l
17. Neutrophils <2.0 x 10^9/l, platelets <100 x 10^9/l, haemoglobin <10 g/dl
18. Known lactose intolerance

Date of first enrolment
23/01/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrooke's NHS Foundation Trust (UK)

Sponsor details

Research and Development Department
Hills Road
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type
Charity

Funder Name
The Evelyn Trust

Funder Name
Cambridge Arthritis Research Endeavour (registered charity number: 802862)

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