

Trial in Rheumatoid Arthritis of Lisinopril

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/04/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/06/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Rheumatoid disease activity score 28 (DAS28)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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) $\leq 100/60$; BP $\geq 180/100$
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 aminotransferase (AST) and alanine aminotransferase (ALT) AST/ALT > 100 IU/l
17. Neutrophils $< 2.0 \times 10^9/l$, platelets $< 100 \times 10^9/l$, 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

United Kingdom

England

Study participating centre

Addenbrooke's Hospital

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Addenbrooke's NHS Foundation Trust (UK)

ROR

<https://ror.org/055vbx86>

Funder(s)

Funder type

Charity

Funder Name

The Evelyn Trust

Funder Name

Cambridge Arthritis Research Endeavour (registered charity number: 802862)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes