

Are the therapeutic effects of homeopathy attributed to the consultation, the homeopathic remedy or both? An exploratory randomised controlled trial in rheumatoid arthritis (RA) patients

Submission date 17/10/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 21/11/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/12/2011	Condition category Musculoskeletal Diseases	☐ Individual participant data

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
Version 20

Study information

Scientific Title

Acronym

Hoorah

Study objectives

The aims of this study are based on the following two hypotheses:

1. Those who receive a homeopathic remedy (be it classical single individualised or complex homeopathy) will experience more benefit in RA endpoints compared with the placebo group
2. Those who receive homeopathy with consultation will experience more benefit in RA endpoints as compared with those who receive homeopathy with no consultation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rheumatoid Arthritis

Interventions

Arm 1: Consultation + individualised homeopathic treatment

Arm 2: Consultation + rheumatoid complex

Arm 3: Consultation + placebo

Arm 4: No consultation + rheumatoid complex

Arm 5: No consultation + placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. 20% improvement from baseline to end of treatment in global RA symptoms (ACR20, a binary outcome) based on the Outcome Measures for Arthritis Clinical Trials (OMERACT)
2. 35% improvement in patient global assessment scores from baseline to the end of treatment

Key secondary outcome(s)

1. 15% improvement from baseline to end of treatment in the Measure Yourself Medical Outcome Profile scores (MYMOP, a continuous variable)
2. Time to flare
3. Four weekly Disease Activity Score
4. Weekly analgesic use, and changes in conventional medication
5. Weekly pain scores
6. Weekly global assessment of symptoms
7. Adverse event monitoring

Completion date

30/04/2007

Eligibility**Key inclusion criteria**

1. Aged over 18
2. Formal diagnosis of RA (American College of Rheumatology [ACR] guidelines) for at least two years
3. On stable medication for at least three months
4. Have a minimum Disease Activity Score (DAS) of over 2.6 (based on Fuchs 28 joint count)
5. Have a Patient Global Assessment (visual analogue scale [VAS]) score of 30 mm or above and at least 3 tender joints
6. Ability to comply with the requirements of the study and to give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Those with severe co-morbidities e.g. cancer that would make their RA symptoms unstable
2. Participation in an investigational trial within 45 days prior to enrolment
3. Those patients having any condition that requires immunosuppressant treatments for the treatment of cancer
4. Those patients taking biological disease-modifying anti-rheumatic drugs (i.e. anti-tumour necrosis factor [TNF])
5. Those classified as functional status IV based on the Classification of Global Functional Status in Rheumatoid Arthritis
6. Those who are currently using homeopathy, or have used homeopathy within the past 3

months

7. Those who are pregnant or hoping to become pregnant or breastfeed within the duration of the study

Date of first enrolment

01/11/2005

Date of final enrolment

30/04/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Complementary Medicine Research Unit

Southampton

United Kingdom

SO16 5ST

Sponsor information

Organisation

University of Southampton (UK)

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Government

Funder Name

Samueli Institute (USA)

Alternative Name(s)

Samueli Institute for Information Biology

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Southampton Complementary Medical Research Trust (UK)

Funder Name

Department of Health (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	01/06/2011		Yes	No
Protocol article	1. protocol	01/06/2004		Yes	No