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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

Registration date
21/11/2005

Overall study status
Completed

Last Edited
21/12/2011

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 end points 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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/11/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110

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
England

United Kingdom

Study participating centre
Complementary Medicine Research Unit
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details

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Sponsor type
University/education

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	1. protocol	01/06/2004		Yes	No
Results article	results	01/06/2011		Yes	No