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Randomised controlled trial of tumour necrosis factor inhibitors against combination intensive therapy with conventional disease modifying anti-rheumatic drugs in established rheumatoid arthritis

Submission date
11/06/2007

Registration date
12/06/2007

Last Edited
29/09/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
http://www.medscinet.net/TACIT/patientinfodocs/Summary%20PIS%20Version%201%20%2820.12.07%29.pdf

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2007-001190-28

Protocol serial number
HTA 06/303/84; KCL (Rheum) TACIT Version 1 (26/01/07)

Study information

Scientific Title
Randomised controlled trial of Tumour necrosis factor inhibitors Against Combination Intensive Therapy with conventional disease modifying anti-rheumatic drugs in established rheumatoid arthritis

Acronym
TACIT

Study objectives
Active Rheumatoid Arthritis (RA) patients, who meet the National Institute for Clinical Excellence (NICE) criteria for treatment with Tumour Necrosis Factor (TNF) inhibitors, will gain equivalent benefit from intensive combination therapy (two or more Disease Modifying Anti-Rheumatic Drugs [DMARDs] and steroids) at substantially less expense and without increased toxicity.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0630384
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/51339/PRO-06-303-84.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research ethics committee of the UCLH A, 20/04/2007, ref: 07/Q0505/57

Study design
Two-arm pragmatic 12-month randomised controlled multi-centred trial using open-label treatments

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions

There will be two treatment algorithms:
1. For TNF inhibitors, and
2. For combination DMARDs
Treatments will be individualised and will depend on patients' responses.

TNF inhibitors:
All three licensed agents - adalimumab, etanercept, and infliximab - will be allowed at standard doses (British National Formulary). The choice of TNF inhibitor will reflect patient's preferences and local circumstances. Methotrexate will also be given to maximise efficacy and (in the case of infliximab) reduce anti-chimeric antibodies. Any patient intolerant to methotrexate may take another DMARD.

Combination DMARDs:
DMARDs from the following list will be used: methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, ciclosporin and gold injections (sodium aurothiomalate) in combinations with proven efficacy over DMARD monotherapy in Randomised Controlled trials (RCTs). For example:
1. Triple therapy with methotrexate (methotrexate-sulfasalazine-hydroxychloroquine)
2. Other methotrexate combinations (methotrexate-ciclosporin, methotrexate-leflunomide and methotrexate-gold)
3. One sulfasalazine combination (sulfasalazine-leflunomide)

Additional monthly steroids (intramuscular [IM] depomedrone [120 mg stat] or equivalent) will also be used if needed.

The duration of treatment is one year and patients are followed for only this year.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Adalimumab, etanercept, infliximab, methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, ciclosporin and gold injections (sodium aurothiomalate)

Primary outcome(s)
Heath Assessment Questionnaire (HAQ).
Primary and secondary outcomes will be measured at baseline (month 0), 6 months and 12 months.

Key secondary outcome(s))
1. Joint damage
2. Quality of life
3. Disease activity
4. Withdrawal rates
5. Adverse effects
6. Economic evaluation:
6.1. Societal costs
6.2. Cost-effectiveness
6.3. Cost-utility

Primary and secondary outcomes will be measured at baseline (month 0), 6 months and 12 months. Patients will be asked to attend monthly for blood monitoring and will be asked a short questionnaire regarding concomitant medication, any tests outside routine monitoring and adverse events within the last month.

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. Males and females aged over 18 years
2. Established RA by the criteria of the American College of Rheumatology
3. Disease duration of at least 12 months
4. Meet NICE criteria for being prescribed TNF inhibitors:
4.1. Disease Activity Score (DAS) over 5.1
4.2. Failure to respond to two DMARDs including methotrexate
4.3. No contra-indications to TNF inhibitors (including possibility of pregnancy)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable or unwilling to give informed consent
2. Failure of, or contra-indications to, all proposed DMARD combinations (including possibility of pregnancy)
3. Serious inter-current illness
4. Patients on high dose steroids (in excess of 10 mg prednisolone or equivalent per day at trial entry)

Date of first enrolment
01/04/2007

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
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SE5 9RJ

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2014		Yes	No
Results article	results	13/03/2015		Yes	No
Results article	cost-effectiveness results	01/03/2020	13/07/2020	Yes	No
Results article	Characterization of missing data patterns and mechanisms	17/09/2022	29/09/2022	Yes	No
Other publications	secondary analysis	26/08/2016		Yes	No
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