ISRCTN90051516 https://doi.org/10.1186/ISRCTN90051516

MARVEL: Modification by Adalimumab of Rheumatoid arthritis Vascular and EndotheLial function

Submission date	Recruitment status	[ ] Prospectively registered
01/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/02/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/06/2017	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Bruce Kirkham

Contact details
Rheumatology Department
Guy's Hospital
London
United Kingdom
SE1 9RT
+44 (0)207 188 5884
bruce.kirkham@gstt.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RJ1 04/0027

Study information

Scientific Title
Modification of vascular disease markers in active rheumatoid arthritis with fully human monoclonal anti-TNF-alpha antibody (Humira® [adalimumab])

Acronym
Marvel

Study objectives
The primary objective of the study is that measures of vascular dysfunction measured by flow mediated dilatation and pulse wave velocity and analysis, will improve after 13 weeks of adalimumab treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guy's Hospital Research Ethics Committee, ref: 2004/01/06

Study design
Longitudinal single-centre open-label observational study

Primary study design
Observational

Secondary study design
Longitudinal

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
All participants under observation receive 40 mg adalimumab subcutaneously every other week (This trial investigates the changes in outcomes below from baseline).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Humira® (adalimumab)

Primary outcome measure
The following will be assessed pre-therapy and at week 0 (i.e. twice pre-therapy), then weeks 13 and 25:
1. Flow-mediated dilatation
2. Pulse wave velocity
3. Pulse wave analysis

Secondary outcome measures
1. Vascular remodeling assessed by carotid artery ultrasound after 25 weeks of treatment
2. Serum risk factors of vascular disease: Fasting lipids, Low Density Lipoprotein (LDL) subclasses, homocysteine, Homeostasis Model Assessment (HOMA) assessment for insulin resistance, Heat Shock Proteins (HSPs), and BiP (immunoglobulin binding protein), assessed pre-therapy and at week 0 (i.e. twice pre-therapy), then weeks 13 and 25
3. Measures of activated endothelial cell activity: Soluble InterCellular Adhesion Molecule (ICAM) and Vascular Cell Adhesion Molecule (VCAM), assessed pre-therapy and at week 0(i.e. twice pre-therapy), then weeks 13 and 25

Overall study start date
01/09/2004

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Subjects who fulfill the British Society of Rheumatology guidelines for TNF blocking therapy in Rheumatoid Arthritis (RA)
2. Subjects who have abnormal vascular function as assessed at the screening visit
3. Men and women >= 18 years of age, with RA as defined by the 1987-revised merican College of Rheumatology (ACR) diagnostic criteria, with a Disease Activity Score (DAS) greater than 5.1
4. Men and women of childbearing potential must use adequate birth control measures (e.g., abstinence, oral contraceptives, intrauterine device, barrier method with spermicide, or surgical sterilization) for the duration of the study
5. Patient must be able to adhere to the study visit schedule
6. The patient must be capable of giving informed consent and the consent must be obtained prior to any screening procedures
7. Must have a chest X-ray within 3 months prior to commencement of adalimumab with no evidence of malignancy, infection or fibrosis

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Women who are pregnant or breast feeding.
2. Use of any investigational drug within 1 month prior to screening or within 5 half-lives of the investigational agent, whichever is longer.
3. Treatment with any other therapeutic agent targeted at reducing TNF (e.g., pentoxifylline, thalidomide, etanercept, etc.) within 3 months of screening.
4. History of diabetes mellitus.
5. History of ischemic heart disease or peripheral vascular disease.
6. Serious infections (such as pneumonia or pyelonephritis) in the previous 3 months. Less serious infections (such as acute upper respiratory tract infection [colds] or simple urinary tract infection) need not be considered exclusions at the discretion of the investigator.
7. Have active TB or have evidence of latent TB (old or latent TB on chest x-ray, without adequate therapy for TB initiated prior to first dose of study drug). Also excluded are patients with evidence of an old or latent TB infection without documented adequate therapy. Patients with a current close contact with an individual with active TB and patients who have completed treatment for active TB within the previous 2 years are explicitly excluded from the trial. Patients with a household member who has a history of active pulmonary TB should have had a thorough evaluation for TB prior to study enrollment as recommended by a local infectious disease specialist or published local guidelines of TB control agencies.
8. Presence of a transplanted organ (with the exception of a corneal transplant >3 months prior to screening).
9. Malignancy within the past 5 years (except for squamous or basal cell carcinoma of the skin that has been treated with no evidence of recurrence).
10. History of lymphoproliferative disease including lymphoma, or signs and symptoms suggestive of possible lymphoproliferative disease, such as lymphadenopathy of unusual size or location (such as nodes in the posterior triangle of the neck, infra-clavicular, epitrochlear, or periaortic areas), or splenomegaly.
11. Known recent substance abuse (drug or alcohol).
12. Poor tolerability of venepuncture required for blood sampling during the study period.

Date of first enrolment
01/09/2004

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust (UK)

Sponsor details
St Thomas' Street
London
England
United Kingdom
SE1 9RT
+44 (0)207 188 8888
bruce.kirkham@gstt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Abbott 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