ISRCTN21046383 https://doi.org/10.1186/ISRCTN21046383

Patient specific biological responses to total joint replacements

Submission date	Recruitment status	[ ] Prospectively registered
24/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/12/2019	Musculoskeletal Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3298

Study information

Scientific Title
Patient specific biological responses to total joint replacements

Acronym
Patient specific biological responses to total joint replacements

Study objectives
This research will be carried out at the University of Leeds and is a collaborative research programme between the Institute of Medical and Biological Engineering and Consultant Orthopaedic Surgeons, Mr Martin Stone (Chapel Allerton) and Mr David Shaw (Bradford Royal Infirmary). Patients will be recruited from two groups, patients awaiting hip replacement operations and patients with long-term polyethylene implants. Approximately 100 patients from each group will be studied.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: CA03/008)

Study design
Single centre non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
Patients awaiting hip replacement will have an additional 30 ml of blood collection pre-operatively. Inclusion in the study will not affect patient care in any way, and the surgical procedure will be the same whether the patient chooses to participate in the study or not. Patients with long-term implants will be invited by letter to attend the clinic to volunteer the additional 30 ml blood sample.

The blood samples will be processed by the researchers at the University of Leeds, where the white blood cells will be isolated and used in culture with real wear particles generated by

articulation. Cytokine production will be measured by enzyme-linked immunospecific assay (ELISA). Approximately 1 x 10^6 cells will be stored for genetic analysis to determine specific base changes in the DNA. The clinical results of the patients will be followed in follow-up clinics.

The control group will comprise approximately 30 healthy volunteers from the research group (iMBE, Faculty of Biological Sciences & School of Mechanical Engineering). A single 30 ml blood sample will be collected from each control subject by trained personel. Collection of blood samples for research purposes is performed routinely and approval has been awarded from the Faculty of Biological Sciences Research Ethics Committee.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cytokine released by primary human macrophages from individual patients in response to 100 cubic micrometers of polyethylene.

Secondary outcome measures
1. Correlation of genotype with clinical outcome of THR surgery
2. Correlation of phenotypic response to cytokine promoter polymorphism genotype
3. Number of patients that are low responders, intermediate responders and aggressive responders to wear particles

Overall study start date
01/09/2009

Completion date
30/06/2010

Eligibility

Key inclusion criteria
Patients with a Charnley hip prosthesis that has been in situ for 10 years

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 200

Key exclusion criteria

Not provided at time of registration

Date of first enrolment
01/09/2009

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great George Street
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research council

Funder Name
Engineering and Physical Sciences Research Council (EPSRC) (UK)

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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