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	3 3	Individual participant data
06/12/2019		Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 preoperatively. 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 1×10^6 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