ISRCTN12207865 https://doi.org/10.1186/ISRCTN12207865

The study of bone cells specifically in osteoarthritis and factors affecting progression

Submission date
02/06/2015

Recruitment status
No longer recruiting

Registration date
15/06/2015

Overall study status
Completed

Last Edited
15/06/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sclerostin is a small protein made by osteocytes (bone cells). It is thought that higher levels of sclerostin may indicate a more progressive osteoarthritis. Here, we want to investigate whether there are any differences in the sclerostin levels in blood and joints of patients undergoing knee replacement surgery (knee arthroplasty) and record other clinical parameters such as pain, function and histological grading of the osteoarthritis. The aim of this study is to investigate the role of the osteocytes in bone disease such as osteoarthritis and to understand the mechanisms that can occur that sometimes contribute to bone loosening around a prosthesis.

Who can participate?
Adults scheduled to have a knee replacement due to osteoarthritis.

What does the study involve?
A small sample of bone that would otherwise be removed and discarded is taken from each participant at the time of their knee replacement surgery. A blood sample is taken at the same time. Both samples are then taken for analysis.

What are the possible benefits and risks of participating?
The bone will only be used for research and the results will not have any effect on health or treatment.

Where is the study run from?
Calvary Wakefield Hospital (Australia)

When is the study starting and how long is it expected to run for?
May 2013 to July 2017

Who is funding the study?
The Australian Orthopaedic Association and Adelaide University (Australia)

Who is the main contact?
Dr Christine Schutz

Contact information

Type(s)
Scientific

Contact name
Dr Christine Schutz

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270 Wakefield St
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ECE006

Study information

Scientific Title
Research into sclerostin serum and synovial levels and other factors in osteoarthritis of the knee. An observational study.

Study objectives
Sclerostin is produced almost exclusively by osteocytes that regulate bone mass. It is hypothesized that higher levels of sclerostin may indicate a more progressive osteoarthritis.. This study aims to observe if there are any differences in serum sclerostin and synovial sclerostin in patients undergoing knee arthroplasty and record other clinical parameters such as pain and function and histological grading of osteoarthritis (OA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Calvary Ethics committee. , 29/05/2013, ref: 13 CHTECR006

Study design
Observational single centre study.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available on this website.

Health condition(s) or problem(s) studied
Osteoarthritis of the knee and its progression.

Interventions
All patients will have diagnosis of Grade 4 OA and consent to bone and blood samples being taken at time of primary knee arthroplasty. The observations are done pre surgery and serum and synovial fluid analysis is at time of surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Whether another joint required replacement due to OA 12 months after surgery. Number of days recorded between surgeries if < 12months
2. Are serum sclerostin or synovial sclerostin levels higher in those with progressive OA defined by additional surgery < 12 months from initial surgery. High sclerostin levels in serum and synovial fluid indicate a progressive form of OA

Secondary outcome measures
To identify if any other factors such as Vit D levels and obesity contribute to variable sclerostin levels.

Vitamin D levels evaluated pre surgery and 12month postoperatively.

Overall study start date
29/05/2013

Completion date
30/07/2015

Eligibility

Key inclusion criteria
1. Diagnosis of OA KL Grade 4
2. Primary knee arthroplasty scheduled.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Rheumatoid arthritis
2. Previous joint surgery for OA

Date of first enrolment
24/07/2013

Date of final enrolment
23/07/2015

Locations

Countries of recruitment
Australia

Study participating centre
Calvary Wakefield Hospital
Adelaide
Australia
5000

Sponsor information

Organisation
Calvary Wakefield Hospital

Sponsor details
300 Wakefield Street
Adelaide
Australia
5000

Sponsor type

Hospital/treatment centre

Website
www.calvarycare.org.au

ROR
https://ror.org/02gt91x70

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Adelaide University (Australia)

Funder Name
Australian Orthopaedic Association

Alternative Name(s)
AOA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Australia

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/02/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration