

# VASO - Vitamin D and arthroplasty surgery outcomes

<b>Submission date</b> 27/03/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/02/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Vitamin D is essential for good health, because it helps our bodies to absorb calcium from the diet. There is a lot of evidence that having enough vitamin D can help prevent many diseases, such as heart disease, bone diseases and cancer. Although vitamins generally come from the diet, in the case of vitamin D, the majority of people actually get most of it from sunlight. Vitamin D deficiency or insufficiency is common in adults in the UK, particularly during the winter months where over 50% of adults are thought to have low Vitamin D levels. There is evidence that patients who are having knee or hip replacement surgery who have low vitamin D levels could have a poorer outcome and a longer stay in hospital. This study is looking at whether checking patient's Vitamin D levels before they have surgery can help to improve outcomes. 180,000 total hip or knee replacement procedures are performed each year in the UK and so if a link exists, the benefits of screening may be significant, as these deficient patients could start taking supplements to correct the deficiency before surgery until six months afterwards in order to improve outcomes.

### Who can participate?

Adults who are scheduled to have hip or knee replacement surgery

### What does the study involve?

Patients have their vitamin D levels measured at the beginning of the study. Those who are found to have low vitamin D levels are then randomly allocated into one of two groups. Those in the first group receive Vitamin D supplementation before surgery until six months after surgery, and those in the second group receive no vitamin D supplements. Participants in both groups are followed up using questionnaires six months after their surgery and have their medical records reviewed in order to assess how well they have recovered.

### What are the possible benefits and risks of participating?

There are no direct benefits from taking part in the study, as currently it is not known whether screening and then treating Vitamin D deficiency before surgery is beneficial. However, it is hoped that the information from the study will help future patients having hip or knee replacement. There are no notable risks involved with participating.

Where is the study run from?  
Five NHS hospitals in the north of England (UK)

When is the study starting and how long is it expected to run for?  
January 2016 to November 2018

Who is funding the study?  
Orthopaedic Research UK (UK)

Who is the main contact?  
Dr Rory Morrison  
rorymorrison@nhs.net

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
33969

## Study information

**Scientific Title**  
A prospective, randomised-controlled feasibility study investigating the benefit of screening for Vitamin D deficiency in a pre-operative elective arthroplasty setting

**Acronym**  
VASO

**Study objectives**  
A vitamin D level below normal (hypovitaminosis D or Vitamin D insufficiency/deficiency) is linked to a poorer outcome whereas a normal level is linked to an improved outcome following primary, elective hip or knee arthroplasty.

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Yorkshire and The Humber - Bradford Leeds Research Ethics Committee, 13/03/2017, ref: 17/YH/0067

### **Study design**

Randomised; Interventional; Design type: Treatment, Screening, Drug

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Specialty: Musculoskeletal disorders, Primary sub-specialty: Other; UKCRC code/ Disease: Musculoskeletal/ Other osteopathies

### **Interventions**

All patients in this feasibility trial will have their Vitamin D level checked before surgery, on the day of surgery and at 6 months after surgery. Those patients who, before their operation, are found to have a Vitamin D level below normal will be randomised to one of two groups.

Intervention group: Participants receive Vitamin D supplementation each day before surgery and for 6 months following surgery. The dosage of Vitamin D given is dependent on the patient's levels.

Deficiency (<25nmol/L): 20,000 units orally twice per week for 8 weeks then 1,600 units orally daily until 6 months following surgery

Insufficiency (25-49nmol/L): 1,600 units orally daily until 6 months following surgery.

Vitamin D levels are rechecked day of surgery and at 6-months following surgery

Control group: Participants receive no supplementation.

Participants are followed up six months post-surgery via questionnaires and medical record review.

### **Intervention Type**

Supplement

### **Primary outcome(s)**

1. Pain and function is measured using the Oxford hip or knee score, collected by written questionnaire at baseline and 6 months
2. Health-related quality of life is measured using the EQ-5D collected by written questionnaire at baseline and 6 months

### **Key secondary outcome(s)**

1. Length of hospital stay is collected from medical notes at endline
2. Medical complications including superficial and deep infection are collected from medical notes at endline
3. Readmission rates within 30 days of primary surgery are collected from medical notes at

endline

4. Return to theatre rate within 30 days is collected from medical notes at endline

5. Mortality at 90-days is collected from medical notes at endline

**Completion date**

30/11/2018

## Eligibility

**Key inclusion criteria**

1. Patients scheduled for primary total hip or knee arthroplasty
2. Aged over 18
3. Presenting at a participating trial site

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

102

**Key exclusion criteria**

1. Lack of mental capacity to understand/comply with study procedures
2. Revision surgery
3. Known contraindication to Vitamin D treatment, e.g. previous diagnosis of sarcoidosis, primary hyperparathyroidism or other hypercalcaemic disorders, allergy
4. Renal impairment with eGFR <30 mL/minute
5. Already taking a Vitamin D supplement

**Date of first enrolment**

04/05/2017

**Date of final enrolment**

30/06/2017

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Wansbeck General Hospital**  
Woodhorn Lane  
Ashington  
United Kingdom  
NE63 9JJ

**Study participating centre**  
**North Tyneside General Hospital**  
Rake Lane  
North Shields  
United Kingdom  
NE29 8NH

**Study participating centre**  
**Hexham General Hospital**  
Corbridge Road  
Hexham  
United Kingdom  
NE46 1QJ

**Study participating centre**  
**James Cook University Hospital**  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**The Friarage Hospital**  
Northallerton  
United Kingdom  
DL6 1JG

**Sponsor information**

## Organisation

Northumbria Healthcare NHS Foundation Trust

## ROR

<https://ror.org/01gfeyd95>

## Funder(s)

### Funder type

Charity

### Funder Name

Orthopaedic Research UK

### Alternative Name(s)

The Orthopaedic Research UK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to a lack of participant consent.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	02/11/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No