

# Prevalence of osteoporosis in Indian patients undergoing elective arthroplasty and spinal procedures

<b>Submission date</b> 14/06/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/06/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/08/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to assess the prevalence of osteoporosis and/or osteopenia in patients undergoing elective arthroplasty and spinal procedures in India. Osteoporosis is a health condition that weakens bones, making them fragile and more likely to break. The stage before osteoporosis is called osteopenia, when bone density is less than normal. Arthroplasty is a surgical procedure to restore the function of a joint.

### Who can participate?

Men aged 60 years and over and women aged 55 years and over undergoing arthroplasty or spinal procedures.

### What does the study involve?

Patients undergo a bone scan to see if they are osteoporotic or osteopenic. Their fracture risk is assessed using an online questionnaire.

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

Checking for osteoporosis in patients undergoing elective arthroplasty and spinal procedures may decrease complications. There is no risk to patients as this is not an interventional study.

### Where is the study run from?

Cadila Healthcare (India)

### When is the study starting and how long is it expected to run for?

February 2019 to June 2020

### Who is funding the study?

Cadila Healthcare (India)

Who is the main contact?  
Dr Sujoy Kumar Bhattacharjee  
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## Contact information

### Type(s)

Public

### Contact name

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### Contact name

Dr Suyash Bharat

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## **Secondary identifying numbers**

ostivia/01

# **Study information**

## **Scientific Title**

A prospective multicenter study on the prevalence of osteoporosis in Indian patients undergoing elective arthroplasty and spinal procedures

## **Acronym**

PROPESI

## **Study objectives**

To determine the preoperative prevalence of osteoporosis and/or osteopenia in Indian patients undergoing prospective elective arthroplasty/spinal procedures and to evaluate overall bone quality in these patients.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 06/07/2019, Sangini Hospital Ethical Committee (Sangini Hospital, First Floor, Santorini Square, B/h Abhishree Complex, Opp. Star Bazar, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat, India; +91 (0)79 40056171; sanginihospitalec@gmail.com), ref: ECR /147/Inst/GJ/2013/RR-16

## **Study design**

Prospective cross-sectional observational open-label multi-centric study

## **Primary study design**

Observational

## **Secondary study design**

Epidemiological study

## **Study setting(s)**

Hospital

## **Study type(s)**

Diagnostic

## **Participant information sheet**

Not available in web format, please contact Dr Suyash Bharat (+91 (0)9760267848) for a hard copy

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

Osteoporosis

## **Interventions**

This is a prospective, multicenter, cross-sectional study that will include males ( $\geq 60$  years) females ( $\geq 55$  years) undergoing arthroplasty or spinal procedures. Bone mineral density (BMD) at the femoral neck and lumbar spine will be measured by dual-energy X-ray absorptiometry (DEXA). The Fracture Risk Assessment Tool (FRAX®) will be used to evaluate fracture risk.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

Bone mineral density measured using DEXA scan in patients undergoing orthopedic procedure at baseline

## **Secondary outcome measures**

Fracture risk measure using FRAX score at baseline

## **Overall study start date**

01/02/2019

## **Completion date**

01/06/2020

# **Eligibility**

## **Key inclusion criteria**

1. Patients giving informed consent to participate in the study
2. Gender - either male or female
3. Age: male  $\geq 60$  years and female  $\geq 55$  years
4. Patients who are undergoing elective orthopedic and spinal surgical procedures

## **Participant type(s)**

Patient

## **Age group**

Senior

## **Sex**

Both

## **Target number of participants**

140

## **Total final enrolment**

127

## **Key exclusion criteria**

1. Not willing or not able to sign informed consent
2. Patients who underwent spine surgery in the last 2 years
3. Patients on concomitant chemotherapy drugs

**Date of first enrolment**

31/07/2019

**Date of final enrolment**

01/06/2020

## **Locations**

**Countries of recruitment**

India

**Study participating centre****Dr Dilip Shah Clinic**

1/7 Kennaway House 63 a Proctor Road

Opp Edubridge International School

Grant Road (e)

Mumbai

India

400004

**Study participating centre****Dr Sandeep Garg Clinic**

c 397, Nirala Nagar

Near Saraswati Shishu Mandir

Lucknow

India

226020

**Study participating centre****Medi Surge Hospital**

Mithakali Circle

Navranpura

Ahmedabad

India

380009

**Study participating centre****Sarvodaya Hospital**

Sector 8, YMCA Road, Faridabad Haryana

Faridabad

India

121006

**Study participating centre**

**Dr Vikas Mehra Clinic**

1501, Sector 33d  
Chandigarh  
India  
160022

**Study participating centre**

**Mordern Ortho Clinic**

Besides Kalinga Stadium  
751, Behera Sahi Road  
Unit 4, Nayapalli  
Bhubaneswar  
India  
751012

**Study participating centre**

**Vikram Hospital**

Anne's College N.o. 71/1, Millers Road  
Bengaluru  
India  
560052

**Study participating centre**

**Dr S Arumugam Clinic**

20, Gopathi Narayanaswami Chetty Road  
Satyamurthy Nagar  
T Nagar  
Chennai  
India  
600017

**Study participating centre**

**Dr Satish Gore Clinic**

1128, Fergusson College Road Model Colony  
Shivajinagar  
Pune  
India  
411016

**Study participating centre****Dr Vinod Agarwal**

Soni House

401, CD Barfiwala Road

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400049

**Sponsor information****Organisation**

Cadila Healthcare (India)

**Sponsor details**

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Jitesh.Bhattacharya@zyduscadila.com

**Sponsor type**

Industry

**Website**<http://www.zyduscadila.com/>**ROR**<https://ror.org/03ktyvw44>**Funder(s)****Funder type**

Industry

**Funder Name**

Cadila Healthcare Ltd

**Results and Publications**

## Publication and dissemination plan

The researchers intend to publish the epidemiological data.

## Intention to publish date

21/07/2022

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Suyash Bharat (suyash.bharat@zyduscadila.com).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>		10/07/2019	08/07/2021	No	No
<a href="#">Results article</a>		26/07/2022	02/08/2022	Yes	No