

# Evaluating fracture risk in asymptomatic and normocalcemic Primary Hyperparathyroidism (PHPT)

<b>Submission date</b> 07/12/2011	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2012	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/03/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Primary hyperparathyroidism (PHPT) is a condition which is not uncommon in middle and older age where the hormone Parathyroid Hormone (PTH) is over produced in the body. This leads to high calcium levels in the blood, which can cause digestive symptoms, kidney stones, psychiatric abnormalities, and bone disease. A cure is achieved by surgically removing the parathyroid gland. PTH can also cause bone thinning (osteoporosis) which can lead to bones breaking easily. Patients with mild PHPT (asymptomatic PHPT) are often monitored rather than have surgery to remove the parathyroid gland(s), particularly if there is only modestly high calcium in the blood and/or there are no symptoms. However, the decision to refer patients for the operation somewhat depends on the effect of PHPT on the bones. Conventionally the bone assessment undertaken is just a measure of bone density (DEXA scan). However, there are now better ways of assessing bone health by determining the risk of fracture (e.g. the FRAX online tool – see: [www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX)). We aim to undertake a full fracture risk assessment using DEXA and FRAX and also measuring an important risk factor for bone fracture – risk of falls. We hope to find out whether the information from these tests affects whether a panel of experts would refer patients for an operation to remove the PTH gland or monitor the situation.

### Who can participate?

Patients aged 50 or over with asymptomatic PHPT.

### What does the study involve?

Participants undergo a DEXA examination, have back x-rays (to detect any previous spine fractures), a falls risk assessment and other basic clinical data will be collected simply in a research clinic, to enable us to make a FRAX fracture risk measure. A panel of specialists then considers all the information and decides whether the new information is enough to recommend a referral for surgery to remove the PTH gland (on the basis of their being high fracture risk) compared with previous bone assessments (bone density measurement by DEXA scan only).

What are the possible benefits and risks of participating?

Participants may benefit if the new assessments lead to a strong recommendation for surgery compared to what would have been advised based on the previous assessments.

Where is the study run from?

Ipswich Hospital NHS Trust (UK).

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

April to July 2012.

Who is funding the study?

Ipswich Hospital NHS Trust R&D Department (UK).

Who is the main contact?

Dr Gavin Clunie

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Gavin Clunie

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2011/125

## Study information

### Scientific Title

Evaluating fracture risk in asymptomatic and normocalcemic Primary Hyperparathyroidism (PHPT): a cohort study

**Acronym**

FRIP

**Study objectives**

To evaluate comprehensively using X-Ray, Dual X-Ray Absorptiometry (DXA), FRAX® fracture risk tool, falls risk assessment and clinical data, what the fracture risk is in patients with PHPT and evaluate whether, by expert consensus, the advice to manage PHPT is changed - essentially the advisability of immediate parathyroidectomy or long-term monitoring of the condition - in comparison to conventional assessment methods (NIH 2002 criteria)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Cross-sectional clinical assessment study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Primary Hyperparathyroidism (PHPT)

**Interventions**

Novel assessment methods: The overall term is 'comprehensive fracture risk assessment'. This uses:

1. Lateral spinal radiographs [Dual X-Ray Absorptiometry (DXA)] to evaluate whether previous spinal fractures have occurred
2. A composite fracture risk calculator/algorithm termed FRAX ([www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX))
3. A falls risk evaluation

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Number of participants where clinical advice for PHPT management is changed by the (study) fracture risk assessment, from expert consensus, compared with conventional assessment methods of fracture risk

**Secondary outcome measures**

Validity of DXA-based VDA (Vertebral Deformity Assessment) in identifying vertebral fracture in comparison to gold-standard radiograph assessment

**Overall study start date**

01/04/2012

**Completion date**

31/07/2012

**Reason abandoned (if study stopped)**

Lack of staff/facilities/resources

## Eligibility

**Key inclusion criteria**

1. Patients >18y old
2. Male or female patients
3. Those who have an established diagnosis of a PHPT or must have been assessed by an Endocrinologist or Metabolic Bone Physician and then recommended to have non-surgical management of their PHPT

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50

**Key exclusion criteria**

1. <18 years old
2. Those unable to give informed consent
3. Prisoners
4. Women who are pregnant or breast feeding
5. Patients with PHPT who would not be suitable for either PTHx medically on safety grounds or

where there are serious concerns about the success of an operation

6. Patients with FHH or other condition causing hypercalcemia

**Date of first enrolment**

01/04/2012

**Date of final enrolment**

31/07/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Ipswich Hospital

Ipswich

United Kingdom

IP4 5PD

## **Sponsor information**

**Organisation**

Ipswich Hospital R&D Dept (UK)

**Sponsor details**

Heath Rd

Ipswich

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05m3qrs33>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Ipswich Hospital NHS Trust R&D (UK)

## **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