ISRCTN66569335 https://doi.org/10.1186/ISRCTN66569335

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

Submission date
07/12/2011

Recruitment status
Stopped

Registration date
10/02/2012

Overall study status
Stopped

Last Edited
14/03/2018

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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). 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
gavin.clunie@doctors.org.uk

Contact information

Type(s)
Scientific

Contact name
Dr Gavin Clunie

Contact details
Ipswich Hospital
Rheumatology Dept
Ipswich
United Kingdom
IP4 5PD
-
gavin.clunie@doctors.org.uk

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)
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 preganant 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
England
United Kingdom
IP4 5PD
-
frances.farnsworth@ipswichhospital.nhs.uk

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