

A population study into the prevalence and genetic profile of patients with chronic pain who do not respond to oral codeine

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/08/2016	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

7230

Study information

Scientific Title

A single site, pilot population study into the prevalence and genetic profile of patients with chronic pain who do not respond to oral codeine

Study objectives

The goal of pain management is to provide symptom relief and improve an individual's level of functioning. Prescription of analgesics follows the World Health Organization (WHO) Pain Relief 3 step ladder. Step one is a non-opioid medication (e.g. paracetamol), step two is a weak opioid (e.g. Codeine phosphate) and step three is an opioid.

It is estimated that 5 - 10% of Caucasians metabolise codeine poorly as a result of non-functioning alleles of the CYP2D6 gene; a further 10 - 15% are termed intermediate metabolisers. Potentially, therefore, up to 25% of a Caucasian population will lack an optimal analgesic response to codeine. The ability to predict clinical efficacy and identify these variations through an easily executed, repeatable, cost effective clinical test would be a valuable tool both to clinicians and patients. The benefits may include enhanced patient compliance due to better clinical response, improved patient safety, and reduced costs.

This is a single site population study to determine the proportion of chronic pain patients who lack an analgesic response to codeine (i.e. codeine non-responders) and to investigate whether the proportion of codeine non-responders in the chronic pain population is greater than the well known figure of 10% seen in the general population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC, 09/01/2009, ref: 08/H1307/132

Study design

Single-centre non-randomised interventional screening and treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Congenital Disorders; Subtopic: Congenital Disorders (all Subtopics); Disease: Clinical Genetics

Interventions

A sample of 150 patients will be enrolled from the Leeds Chronic Pain Clinic over 18 months. Participants will attend the pain research clinic at Seacroft Hospital Leeds on three separate occasions (screening, treatment visit, end of study visit). Their participation will be no longer than 15 days from screening to follow up. Each participant will be given 5 days of oral codeine, complete pain questionnaires and provide saliva, oral fluid and urine samples for genetic testing and codeine levels.

Intervention Type

Other

Phase

Phase IV

Primary outcome(s)

Proportion of chronic pain

Key secondary outcome(s)

Codeine non-responsiveness

Completion date

15/09/2010

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2009

Date of final enrolment

15/09/2010

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Seacroft Hospital

Leeds

United Kingdom

LS14 6UH

Sponsor information

Organisation

Leeds Teaching Hospitals NHS Trust (UK)

ROR

<https://ror.org/00v4dac24>

Funder(s)

Funder type

Industry

Funder Name

Napp Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No