ISRCTN16874724 https://doi.org/10.1186/ISRCTN16874724

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
Proportion of chronic pain

Secondary outcome measures
Codeine non-responsiveness

Overall study start date
01/09/2009

Completion date
15/09/2010

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 150

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
England

United Kingdom

Study participating centre
Seacroft Hospital
Leeds
United Kingdom
LS14 6UH

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust (UK)

Sponsor details
Research and Development
34 Hyde Terrace
Leeds
England
United Kingdom
LS2 9LN

Sponsor type
Hospital/treatment centre

Website
http://www.leedsteachinghospitals.com/

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Industry

Funder Name
Napp Pharmaceuticals (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

Study outputs

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