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A randomised, placebo-controlled, double-blind trial of ondansetron in renal itch

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/07/2009	Urological and Genital Diseases	

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
RRCC144R MURPHY

Study information

Scientific Title

Study objectives
Patients will be randomised to receive either ondansetron 8 mg tbs or a lactulose placebo tbs for one week. Lactulose is the other constituent of ondansetron preparations. Neither the patient or investigating doctors will be aware of which treatment the patient has received. Following a one week wash-out period the patients will be switched to the other treatment according to the cross-over design. Patients will be followed up for one week following cessation of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Renal itch

Interventions
1. Ondansetron 8 mg tbs
2. Lactulose placebo tbs for one week

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Ondansetron, lactulose

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/01/2000

Completion date
11/01/2000

Eligibility

Key inclusion criteria
Twenty-five patients will be recruited from the renal dialysis unit, only patients on haemodialysis will be included. Patients with a history of pruritus for more than eight weeks will be given a visual analogue scale to assess the severity of pruritus twice a day for one week. Those patients with a mean peak value greater than 5 out of 10 for the last five days of the week will be included.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
25

Key exclusion criteria
Patients will be excluded if they have concomitant dermatological disease associated with pruritus as assessed by a dermatologist (MM) or another metabolic cause of itch.

Date of first enrolment
06/01/2000

Date of final enrolment
11/01/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Dermatology
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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?
Results article	results	01/02/2003		Yes	No