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Ondansetron for the treatment of irritable bowel syndrome (IBS) with diarrhoea (IBS-D): identifying the responder

Submission date 31/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2010	**Overall study status** Completed	
Last Edited 26/07/2016	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00745004

Clinical Trials Information System (CTIS)
2008-000623-25

Protocol serial number
6965

Study information

Scientific Title
A randomised interventional multicentre trial of ondansetron versus placebo in the treatment of patients with irritable bowel syndrome (IBS) with diarrhoea (IBS-D)

Acronym
Ondansetron for IBS-D

Study objectives
Irritable bowel syndrome (IBS) is a common problem, with often distressing symptoms that can result in a reduced quality of life. This is a two centre randomised double blind placebo controlled crossover trial of Ondansetron in IBS-D. The aim is to identify clinical, laboratory, and magnetic resonance imaging (MRI) scan features that will predict response in clinical practice. The primary outcome measure is a change in stool average stool consistency in the last 2 weeks of treatment of Ondansetron versus placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2, 10/11/2008, ref: 08/H0408/134

Primary study design
Interventional

Study design
Randomised interventional multicentre treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Double blind placebo, this is a randomised double blind placebo controlled trial
1. A 1 week screening period where the subject completes a daily stool diary
2. Treatment period 1 (5 weeks) where the subject receives either placebo or 4 mg of ondansetron titrated to a dose of min 4 mg every other day, max 8 mg three times a day
3. A 2 week washout
4.A second treatment period (5 weeks) where the subject receives either placebo or active therapy with ondansetron depending on which therapy was administered in treatment

Study Entry: Single Randomisation only

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Ondansetron

Primary outcome(s)
Difference in average stool consistency in the last 2 weeks of treatment of Ondansetron versus placebo

Key secondary outcome(s)
Measured against the primary endpoint in the final 2 weeks of each treatment period:
1. Proportion of patients preferring ondansetron versus placebo
2. Proportion wanting to continue with ondasetron

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Patients with IBS-D meeting the Rome III criteria
2. Patients able to give informed consent
3. Female patients of child bearing potential are willing to use at least one highly effective contraceptive method
4. Aged 18 years and over, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Women who are pregnant or breast feeding
2. Patients unable to stop anti-diarrhoeal drugs
3. Patients currentluy in, or have been in another clinical trial in the previous 3 months

Date of first enrolment
01/01/2009

Date of final enrolment

31/01/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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?
Results article	results	01/10/2014		Yes	No
HRA research summary			28/06/2023	No	No