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HalOPeridol Effectiveness in ICU delirium - the HOPE-ICU trial

Submission date	Recruitment status	[_] Prospectively registered
21/01/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/01/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/01/2015	Injury, Occupational Diseases, Poisoning	

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
9331

Study information

Scientific Title
A randomised, double-blind, placebo controlled trial to compare the early administration of intravenous haloperidol versus placebo in the prevention and treatment of delirium in critically ill ventilated patients

Acronym
HOPE-ICU trial

Study objectives
This is a randomised placebo controlled, double blind, clinical effectiveness trial. It is designed to evaluate the effect of the early administration of haloperidol on duration of delirium in 142 mechanically ventilated patients at high risk of delirium. Delirium in intensive care patients is an independent risk factor for an increased in mortality and long term cognitive impairment. There is no definitive evidence to support the use of haloperidol to treat ICU delirium and the evidence of benefit and potential effects is conflicting.

As of 08/02/2011 this record was updated to include new trial dates, as the previous ones are incorrect. The initial incorrect trial dates were as follows:
Initial anticipated start date: 02/11/2010
Initial anticipated end date: 30/09/2012

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee approved on the 7th September 2010 (ref: 10/H0505/65)

Study design
Single centre randomised interventional placebo-controlled prevention and treatment phase II trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Critical Care

Interventions
Haloperidol 2.5 mg intravenously or 0.5 ml normal saline intravenously 8 hourly for up to 14 days or until the patient screens negative for delirium for 48 hours using the CAM-ICU.

Follow up length: 6 months
Study entry: single randomisation only

Intervention Type
Drug

Phase
Phase II

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

Primary outcome measure
Delirium/coma free days, measured at 14 days

Secondary outcome measures
1. Incidence of delirium
2. Delirium/coma free days in first 28 days
3. Number of ventilator free days at 28 days
4. Length of critical care and hospital stay
5. Mortality and cause of death at 6 months
6. Organ failure free days
7. Cognitive decline
8. Health related quality of life

Overall study start date
01/10/2010

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Patients requiring mechanical ventilation within 72 hours of admission
2. Male and female, aged 18 - 99 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 142; UK sample size: 142

Key exclusion criteria
1. Allergy to haloperidol
2. Chronic antipsychotic use
3. QTc greater than 500 msecs
4. History of torsades de pointes
5. Family history of dystonic reactions
6. Moribund and not expected to survive
7. Uncomplicated elective surgery
8. Expected to stay less than 48 hours
9. Moderate/severe dementia
10. Pregnancy
11. Parkinsons disease
12. Structural brain damage
13. History of neuroleptic malignant syndrome
14. Patients who do not understand English

Date of first enrolment
01/10/2010

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
60 Vicarage Road
Watford
United Kingdom
WD18 0HB

Sponsor information

Organisation
West Hertfordshire Hospitals NHS Trust (UK)

Sponsor details
60 Vicarage Road
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England
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-
Fiona.smith@whht.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.westhertshospitals.nhs.uk

ROR
https://ror.org/03e4g1593

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/09/2013		Yes	No
HRA research summary			28/06/2023	No	No