HalOPeridol Effectiveness in ICU delirium - the HOPE-ICU trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/01/2011		☐ 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

Contact name

Dr Valerie J Page

Contact details

60 Vicarage Road Watford United Kingdom WD18 0HB

valerie.page@whht.nhs.uk

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

Delirium/coma free days, measured at 14 days

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre 60 Vicarage Road

Watford United Kingdom WD18 0HB

Sponsor information

Organisation

West Hertfordshire Hospitals NHS Trust (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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes