# 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		
<b>Last Edited</b> 09/01/2015	Condition category Injury, Occupational Diseases, Poisoning	Individual participant data		

## 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

**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 Watford England United Kingdom WD18 0HB

\_

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	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2013		Yes	No
HRA research summary			28/06/2023	No	No