

# HalOPERidol Effectiveness in ICU delirium - the HOPE-ICU trial

<b>Submission date</b> 21/01/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/01/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/01/2015	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**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?
<a href="#">Results article</a>	results	01/09/2013		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No