# Heroin Assisted Treatment in Andalusia: The PEPSA Trial

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
03/08/2008	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
19/02/2009	Completed	[X] Results
Last Edited	Condition category	Individual participant data
16/11/2009	Mental and Behavioural Disorders	

#### Plain English summary of protocol

Not provided at time of registration

#### Study website

http://www.easp.es/pepsa

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

# EudraCT/CTIS number

2005-002896-33

#### **IRAS** number

#### ClinicalTrials.gov number

#### Secondary identifying numbers

N/A

# Study information

#### Scientific Title

Efficacy of prescribed injected diacetylmorphine in the Andalusian trial: responders and non-responders evaluated using a multi-domain outcome index

#### Acronym

**PEPSA** 

#### **Study objectives**

The impact of intravenous diacetylmorphine (DAM) plus oral methadone is better than a treatment with oral methadone alone on the physical and mental health and social integration of refractory opioid addicts.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics board of the Hospital Virgen de las Nieves, approved on 01/08/2001 (ref: 01/15.2)

#### Study design

Open randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

## Study setting(s)

Other

# Study type(s)

Treatment

## Participant information sheet

# Health condition(s) or problem(s) studied

Refractory opioid addicts

#### **Interventions**

Participants in the experimental group received DAM (heroin) injection twice a day, plus oral methadone once a day (to be taken at home) for 9 months. The control group received only oral methadone to be taken once a day.

#### Dosage:

The two groups received an equivalent opioid dose. Among treatment completers, an average DAM dosage of 274.5 mg/day (range: 15-600 mg) and an average methadone dosage of 42.6 mg /day (range 18-124 mg) were prescribed for the experimental group. The daily methadone dosage in the control group was 105 mg/day (range: 40-180 mg).

As a result, the approximate mean daily total equivalent dosage of DAM/day for the experimental group was between 395.5 and 414.5 mg/day; for the control group, it was between 361 and 400 mg/day.

Of the 62 participants, 44 completed the treatment and 50 patients were analysed.

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#### Intervention Type

Drug

#### Phase

Not Applicable

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

Diacetylmorphine (DAM; heroin), methadone

#### Primary outcome measure

A dichotomous multidimension outcome (MDO) index was determined by protocol as a primary outcome variable, imputing success when the patient showed at least 20% improvement at 9 months, compared with the baseline values, in general health or psychological or family adjustment, without a deterioration superior to 20% in any of these dimensions evaluated with the respective Addiction Severity Index (ASI) composite scores.

#### Secondary outcome measures

The following were assessed before randomisation, at 3, 6 and 9 months (end of the trial):

- 1. Physical and mental health, assessed by the Opiate Treatment Index (OTI), Symptom Checklist (SCL) and Maudsley Addiction Profile (MAP)
- 2. Psychosocial adjustment, assessed by the OTI and ASI
- 3. Treatment retention
- 4. Illegal activities, assessed by the ASI
- 5. Illicit drug use, assessed by the OTI and ASI
- 6. Quality of life, assessed by the Health Related Quality of Life 12-item Short Form (SF-12)

#### Overall study start date

15/02/2003

#### Completion date

15/12/2004

# **Eligibility**

#### Key inclusion criteria

- 1. Both males and females, 21 years or older
- 2. Long-term opioid-dependent persons who had not been benefited from other treatments

Potential participants were interviewed in squares, soup kitchens and methadone dispensaries by outreach workers and peers, who suggested they make an appointment with a PEPSA physician.

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

## Target number of participants

62

#### Key exclusion criteria

- 1. Non-agreement to participate
- 2. Psycho-social impairment to answer the questionnaires
- 3. Current medical, social or legal situation that is likely to result in an discontinuation period longer than the study period (9 months)

#### Date of first enrolment

15/02/2003

#### Date of final enrolment

15/12/2004

# Locations

#### Countries of recruitment

Canada

Spain

Study participating centre School of Population and Public Health

Vancouver, BC Canada V6Z 1Y6

# Sponsor information

#### Organisation

Drug Commission, Council for Equality and Social Welfare (Spain)

#### Sponsor details

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#### Sponsor type

Government

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Committee on Drug Dependence, Carlos III Health Institute (Spain)

# **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 Date Peer Patient-

type	Details	created added	reviewed	? facing?
<u>Protocol</u> <u>article</u>	protocol	01/05 /2004	Yes	No
Results article	main results:	01/09 /2006	Yes	No
Other publication	review including data from this trial <u>s</u>	01/07 /2007	Yes	No
Results article	results	01/07 /2008	Yes	No
Results article	results, comparing the baseline data from Canadian sample with the European trials, including the data from this trial:	01/11 /2008	Yes	No
Results article	results	14/08 /2009	Yes	No