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Heroin Assisted Treatment in Andalusia: The PEPSA Trial

Submission date	Recruitment status
03/08/2008	No longer recruiting
Registration date	**Overall study status**
19/02/2009	Completed
Last Edited	**Condition category**
16/11/2009	Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.easp.es/pepsa

Contact information

Type(s)
Scientific

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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
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Sponsor information

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

Sponsor details
C/o Andrés Estrada Moreno
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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	Date	Peer	Patient-

type	Details	created	added	reviewed?	facing?
Protocol article	protocol	01/05/2004		Yes	No
Results article	main results:	01/09/2006		Yes	No
Other publications	review including data from this trial	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