

Methadone induction in primary care

Submission date 22/10/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 09/02/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/03/2017	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

People who are addicted to opiates such as heroin can be prescribed a heroin substitute such as methadone or buprenorphine to help them stop their drug use. The rapid increase in the use of opioid substitution treatment for drug users, mainly achieved through prescribing buprenorphine in primary care, has been successful in reducing HIV prevalence among drug users but is still inadequate for reducing the spread of hepatitis C. In France methadone treatment can currently only be started in drug centres but GPs can prescribe methadone after stabilisation of dosages. The main aim of this study is to compare patients who start methadone treatment in primary care and patients who start methadone treatment in Specialized Drug Addiction Treatment Centers, in order to find out whether the proportion of patients not using opioids after 1 year of treatment is the same. The other aims include assessing adherence to treatment, addictive behaviours, quality of life, psychiatric conditions, reduction in criminal acts, and cost effectiveness.

Who can participate?

Patients aged between 18 and 70 who need methadone treatment for their opioid dependence, and who have either never received methadone, have not had any methadone for at least 1 month, or need to switch from buprenorphine to methadone

What does the study involve?

Participants are randomly allocated to start taking methadone either in primary care or a specialised centre for opioid dependence. After stabilisation of dosages the participants can choose whether to change groups. The study lasts for 12 months with examinations and interviews at the start of the study and after 3, 6 and 12 months. The prevalence of daily opioid use after one year of treatment is compared between groups. The prevalence of other addictive behaviors, adherence to treatment, improvement in quality of life, psychiatric conditions, reduction in criminal acts and cost-effectiveness are also assessed.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

ANRS - French Aids Research Agency (France)

When is the study starting and how long is it expected to run for?

January 2009 to January 2012

Who is funding the study?

1. ANRS - French Aids Research Agency (France)
2. French Ministry of Health (France)

Who is the main contact?

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Contact information

Type(s)

Scientific

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ClinicalTrials.gov (NCT)

NCT00657397

Protocol serial number

2008-001338-28

Study information

Scientific Title

Induction of methadone in primary care (ANRS-METHAVILLE): a phase III randomized non-inferiority trial in France

Study objectives

The main hypothesis is that the delivery model used for first prescription (primo-prescription) of methadone does not influence injection relapses nor treatment's effectiveness. More specifically, we hypothesize a non-inferiority after one year treatment in patients who were inducted in primary compared to those who initiated methadone in specialized centers in terms of prevalence of daily opioid users.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Commissions for the Protection of Person (Comités de Protection des Personne) (CPP.IDF.VI), 29/05/2008, ref: 08-015

Study design

Randomised multicentre non-inferiority control trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Opioid dependence

Interventions

Intervention group: 14 day induction of methadone treatment in primary care by a trained General Practitioner.

Control group: 14 day induction of methadone treatment in Specialized Drug Addiction Treatment Centers

After the 14 induction days, the participant could choose to remain to the allocated setting or to change to the other one (primary care or specialized center).

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Methadone

Primary outcome(s)

1. Daily opioid use
2. Method of measurement: Opiate Treatment Index (OTI) - a multi-dimensional questionnaire based in patients self-report (REF OTI- Darke et al, 1992) 12 months after enrolment (visit M12)
3. Prevalence (%) of opioid users at M12

Key secondary outcome(s)

1. The prevalence of other hepatitis C virus (HCV) risk transmission practices is being documented using a series of questions extracted from a standardized questionnaire specific for this purpose, the BBV-TRAQ (Fry and Lintzeris, 2003; Tucker et al, 2004) at M12
2. Other indicators relevant for the purpose of this thesis are being collected:
 - 2.1. Depressive symptoms Becks H questionnaire (Beck et al, 1985)
 - 2.2. Alcohol consumption with the AUDIT questionnaire (Saunders et al, 1993)
 - 2.3. Patient-health care provider relationship (Smith et al, 2006)

2.4. Adherence to methadone

2.5. Urinary drug screening and socio-demographic information on history of incarceration and contact with associations

Completion date

02/01/2012

Eligibility

Key inclusion criteria

1. Between 18 and 70 years old
2. Opioid dependent and with an indication for methadone treatment
3. Being naive or without any previous methadone treatment during the last 30 days or having failed with buprenorphine treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Contraindication to methadone treatment
2. Co-dependence on alcohol and benzodiazepines
3. Inmates
4. Pregnant women
5. Individual in irregular situation or who cannot be joined by phone

Date of first enrolment

02/01/2009

Date of final enrolment

02/01/2012

Locations

Countries of recruitment

France

Study participating centre
23 rue Stanislas Torrents
Marseille
France
13006

Sponsor information

Organisation

ANRS - French Aids Research Agency [Agence Nationale de Recherche sur le Sida] (France)

ROR

<https://ror.org/01kv58h76>

Funder(s)

Funder type

Research organisation

Funder Name

ANRS (French Aids Research Agency) (France)

Alternative Name(s)

National Agency for AIDS Research, National Agency for Research on AIDS and Viral Hepatitis, National Agency of Research on AIDS and Viral Hepatitis, ANRS | Maladies infectieuses émergentes, ANRS MIE, ANRS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

France

Funder Name

Ministry of Health (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2014		Yes	No
Results article	results	10/09/2014		Yes	No
Results article	results	13/11/2014		Yes	No
Results article	results	05/04/2016		Yes	No
Protocol article	protocol	28/06/2012		Yes	No