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Methadone induction in primary care

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

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?
Dr Patrizia Carrieri
pmcarrieri@aol.com

Contact information

Type(s)
Scientific

Contact name
Dr Patrizia Carrieri

Contact details
23 rue Stanislas Torrents
Marseille
France
13006
+33 (0)4 96 10 28 75
pmcarrieri@aol.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00657397

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 Practitionner.
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 measure
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

Secondary outcome measures
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

Overall study start date
02/01/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
197

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)

Sponsor details
c/o Ms Isabelle Porteret
101 rue de Tolbiac
Paris
France
75013
+33 1 53 94 60 09
Isabelle.porteret@anrs.fr

Sponsor type
Research organisation

Website
http://www.anrs.fr/

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
France

Funder Name
Ministry of Health (France)

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/06/2012		Yes	No
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