ISRCTN61294249 https://doi.org/10.1186/ISRCTN61294249

A randomised controlled trial, economic evaluation and qualitative study of supervised consumption in patients managed with opiate maintenance treatment (the Super-C study)

Submission date
23/01/2008

Recruitment status
No longer recruiting

Registration date
05/02/2008

Overall study status
Completed

Last Edited
28/04/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title

Acronym
Super-C

Study objectives
Null hypothesis: that there is no difference in proportion of patients retained in treatment over three months between those supervised (intervention) and those receiving unsupervised consumption (control) of opiate maintenance therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Hertfordshire Research Ethics Committee, 11/01/2008, ref: 07/H0311/198

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Substance misuse - opiate dependance

Interventions
The intervention group will be supervised (i.e. observed by their dispensing pharmacist) consuming whichever opiate replacement drug that they have been prescribed (either methadone or buprenorphine). This intervention will occur daily (6 - 7 days/week) and will continue for three months.

The control group will be dispensed their opiate replacement drug (methadone or buprenorphine) on a daily basis (6 - 7 days per week). Their consumption of this will be supervised for the first week. After that they will be able to consume their medication in private (i.e. unsupervised).

Please note the choice of opiate maintenance therapy (methadone or buprenorphine) and dose of drug used for each participant, is a clinical decision and does not form part of this study (though it will be recorded in each case).

Follow-up will continue for six months.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Buprenorphine, methadone

Primary outcome(s)
Retention in treatment at three months.

Key secondary outcome(s)
1. Retention in treatment at six months (from clinic records)

All others measured at 3 months only, through follow-up interview, data from keyworkers (Christo score) or clinic records/routine data:
2. Evidence of reduction in use of illicit opioids (urine testing and Maudsley addiction profile results [MAP])
3. Use of other illicit drugs and alcohol use (urine testing results from clinic records and MAP results)
4. Addiction severity and social functioning (measured by Christo score - provided by keyworkers)
5. Changes in psychological functioning (measured by the MAP)
6. Changes in quality of life measured by the 12-item short form health survey (SF-12) and the capability index (self-complete questionnaires)
7. Changes in criminal behaviour (MAP)
8. Adverse events (emergency hospital attendance [accidency and emergency department attendance or hospital admission] with symptoms of drug overdose/death)
9. Average dose of drug prescribed over treatment period (clinic records)
10. Self-report satisfaction with pharmacy (3-month follow-up drug use questionnaire)
11. Self-report drug compliance and diversion (3-month follow-up drug use questionnaire)
12. Monthly assessment of injecting sites for those injecting at baseline (clinic records)
13. Treatment outcomes profile (clinic records using National Treatment Agency form which is collected routinely by drug service)

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Confirmed symptoms of opioid dependency (including toxicological investigations)
2. Electing for maintenance treatment (as opposed to other forms of management, e.g., detoxification) with either methadone or buprenorphine
3. Aged 16 years or older, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Chronic injectors refusing oral therapy
2. Under 16 years
3. Hypersensitivity to both buprenorphine and methadone
4. Treatment with suboxone (as this is not routinely supervised)
5. Severe medical condition making treatment hazardous in the opinion of the treating physician
6. Incapacity to give informed consent
7. Maintenance treatment during last four weeks
8. Those patients deemed to definitely require supervised consumption at discretion of the treating physician (such as homeless, those with a drug-using partner not in treatment)
9. Those patients where supervised consumption of their agreed treatment can not be provided for reasons of geographical placement (e.g. no provision of supervised consumption in the local pharmacy)

Date of first enrolment
01/03/2008

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Medicine, Health Policy & Practice
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Sponsor information

Organisation
Hertfordshire Partnership NHS Foundation Trust (UK)

ROR
https://ror.org/0128dmh12

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (UK) - Research for Patient Benefit Programme

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?
Results article	results	01/01/2014		Yes	No
Results article	results	01/04/2014		Yes	No