Co-prescribed heroin and methadone supplemented with with contingency management:
A randomized controlled trial.

Gepubliceerd: 01-09-2014 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24738

Bron
NTR

Aandoening

heroin dependency
cocaine
addiction
heroin-assisted treatment
contingency managemen

heroïne-afhankelijkheid
cocaïne
verslaving
behandeling met heroïne op medisch voorschrift
contingentie management

Ondersteuning

Primaire sponsor: Central Committee on the Treatment of Heroin Addicts (CCBH), Utrecht University Medical Center
Overige ondersteuning: Ministry of Health, Welfare and Sports, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure will be the maximum number of consecutive weeks of cocaine metabolite-free urine samples during the first six months of the trial.

Toelichting onderzoek

Doel van het onderzoek

We propose to evaluate the beneficial effects of adding a contingengy management (CM) intervention, aimed at a reduction of cocaine consumption, to the current heroin-assisted treatment. This intervention – combined heroin-assisted treatment plus CM – will be compared to heroin-assisted treatment alone in a study population of chronic, treatment-resistant heroin dependent patients. The study questions are:

1. What is the effectiveness – in terms of reduced cocaine consumption and in terms of improvements in the areas of health and social functioning – of six months of ongoing heroin-assisted treatment plus contingency management, compared to six months of ongoing heroin-assisted treatment alone, in chronic, treatment-resistant heroin dependent patients?

2. What is the effect – in terms of cocaine consumption and in terms of health and social functioning – of terminating the contingency management intervention after six months?

3. What is the cost-utility of heroin-assisted treatment plus contingency management, compared to heroin-assisted treatment alone?

Onderzoeksopzet

The primary timepoint is 6 months after the start of the experimental study phase.
The secondary timepoint is 12 months after the start of the experimental study pahse (at the end of the 6 months naturalistic follow-up phase).

Onderzoeksproduct en/of interventie

Control group: Heroin-assisted treatment alone.

Subjects assigned to heroin-assisted treatment alone will receive a treatment offer of injectable or inhalable heroin (maximum of 400 mg per prescription and 1,000 mg per day) in combination with oral methadone. The co-prescribed heroin and methadone have to be used in the treatment center, under the supervision of the treatment-staff.

Experimental group: Heroin-assisted treatment plus contingency management.
Subjects assigned to heroin-assisted treatment plus CM will receive the same treatment offer as those in the heroin-assisted treatment alone condition, but with the addition of monetary vouchers for each cocaine-negative urine sample. The voucher value will be based upon an escalating schedule, with a reset after a cocaine-positive urine sample. The monetary vouchers obtained during the trial have to be spend on personal care or improvement of the (physical, mental or social) health status, after consent of the treatment staff.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Treatment-resistant heroin dependency, as indicated by:

a. a history of heroin dependency (DSM-IV) of at least five years;

b. a minimum dose level of 50 mg (inhaling heroin) or 60 mg (injecting heroin) of methadone per day for an uninterrupted period of at least four weeks in the previous five years;

c. in the previous year registered in a methadone program, and during the previous six months in regular contact with the methadone program;

d. chronic heroin addiction and unsuccessfully treated in methadone maintenance treatment;

e. daily or nearly daily use of illicit heroin;

f. poor physical, and/or mental, and/or social functioning.

2. Clinically relevant cocaine use, as indicated by:

a. at least one cocaine-positive urine sample during the 4-8 weeks qualification period prior to the start of the heroin-assisted treatment, and

b. at least four days of cocaine use in the month preceding the start of the heroin-assisted treatment, according to self-report, and

c. at least two cocaine-positive urine samples in the month preceding the start of the experimental or control treatment.
During this month, a total of 12 urine samples will be requested, of which a minimum of 10 samples must be provided by the patient, and

d. at least four days of cocaine use in the month preceding the start of the experimental or control treatment, according to self-report.

3. Heroin is used through intravenous injection or inhalation.

4. At least 25 years old.

5. Citizen or legal resident in the Netherlands.

6. Registered as a resident in the city area of the treatment site for at least three years.

7. Willing and able to attend the treatment site for the required study assessments and other procedures.

8. Willing to attend the treatment site at least three days a week.

9. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not meeting all inclusion criteria.

2. Severe medical, psychiatric or psychosocial problems which constitute a contra-indication for participation.

3. Severe medical, psychiatric or psychosocial problems which may interfere with the conduct of the study.

4. A history of aggressive behavior which is expected to interfere with the conduct of the study and/or the participation in the study of other subjects.

5. Pregnancy or continued lactation, or desire to become pregnant in the near future.

6. Unwilling to attend the treatment site for the required assessments.

7. The heroin dependency is of secondary importance compared to an existing non-opiate dependency.

8. The patient is unwilling to use the prescribed heroin in the treatment site.

9. A period of voluntary heroin abstinence of at least two months in the previous year.

10. Patients requiring a dose of prescribed heroin exceeding 1000 mg per day.

11. Patients unable to understand the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2006
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	01-09-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4560
NTR-old	NTR4728
Ander register	: CCMO05.2182/MA/P05.0820C

Resultaten