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Consequences of prolonged diacetylmorphine (DAM; pharmaceutical heroin) take home for individuals with severe opioid use disorder

Submission date
14/06/2023

Recruitment status
No longer recruiting

Registration date
14/06/2023

Overall study status
Completed

Last Edited
03/05/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
In Switzerland, patients in Opioid Agonist Treatment (OAT) were originally only allowed to take home diacetylmorphine (DAM) medication for a maximum of two days. However, due to the Corona pandemic, the government issued a special permit that extended the take-home period to up to seven days for stable DAM patients. The purpose of this study was to understand the effects of this change in medication dispensing on the patients' medical and social stability. Additionally, the study aimed to identify any patient characteristics that may contribute to better stability when given a take-home period of seven days.

Who can participate?
All patients at our facility who qualified for these extended doses based on their stability and who gave informed consent were eligible to participate.

What does the study involve?
We gathered data from old medical records (retrospective data analysis) to find answers to our study question.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Arud Centre for Addiction Medicine Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
May 2020 to May 2022

Who is funding the study?
Arud Centre for Addiction Medicine Zurich (Switzerland)

Who is the main contact?
Dr Franciska Brezan, f.brezan@arud.ch

Contact information

Type(s)
Scientific

Contact name
Dr Franciska Brezan

ORCID ID
https://orcid.org/0000-0002-6246-0788

Contact details
Schützengasse 31
Zürich
Switzerland
8001
+41 762765678
f.brezan@arud.ch

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2021-007006

Study information

Scientific Title
Prolonged DAM take home in the time of Covid-19 - harm reduction or increase? Results of a retrospective chart review

Study objectives
Prolonged DAM take home does not lead to drug, medical or social destabilization.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/06/2021, Swissethics (Stampfenbachstrasse 121, Zurich, 8090, Switzerland; +41 432597970; info@swissethics.ch), ref: 2021-007006

Study design
Single centre retrospective chart review

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Effects of prolonged DAM take home in patients with diacetylmorphine as opioid agonist therapy.

Interventions
A retrospective analysis of medical records was conducted at the Arud Centre for Addiction Medicine in Zurich, Switzerland. This outpatient center is the largest provider of Opioid Agonist Treatment (OAT) in the country, with 320 diacetylmorphine (DAM) patients receiving treatment during the study. The treatment regimen at the center varies based on the patients' medical and social stability. Some patients visit the center multiple times a day, while others receive take-home medication that lasts for up to one month. Initially, take-home medication for DAM was limited to two days until a special permit was introduced.

The maximum daily dose of DAM at our center is 1800mg, with a few exceptions for patients who metabolize the medication quickly. If patients report losing their carry medication, additional doses are provided to prevent withdrawal symptoms. However, if patients require additional dispensing more than twice per quarter, regardless of the reason, they lose their take-home privileges and must visit the center daily for at least one month.

The study included all patients who were receiving oral DAM, deemed stable by their therapists, and qualified for a prolonged take-home period of seven days. These patients had been on oral DAM since at least March 19th, 2019, without any treatment interruptions until March 18th, 2021. Patients who only received injectable DAM take-home were not included in the analysis due to their small numbers.

In the retrospective analysis, data from the year following the implementation of prolonged take-home (referred to as period 2, from March 19th, 2020, to March 18th, 2021) were compared with data from the equivalent previous year (referred to as period 1, from March 19th, 2019, to March 18th, 2020).

The electronic medication prescription and dispensing software MAP (Medication Dispensing Program), custom-developed by ITW Informatik AG, was used at our institution. Through manual review of dispensing records, the following information was extracted: First, the prescribed daily dose of DAM was collected on the first and last day of period 1 and on the last day of period 2. The intravenous DAM dose was converted to an oral dose using a conversion factor of two to determine the cumulative dose. Second, the number of additional dispensing occurrences was determined for each observation period separately. Additionally, the number of prolonged take-home days (maximum of 7) was recorded at the end of period 2. Prolonged take-home privileges were reduced if there were more than two additional dispensing occurrences per quarter, if there was a decline in physical or mental health as assessed during therapist contacts, or if the patient voluntarily requested more frequent visits to the center. Electronic records were used to determine if DAM was also consumed intravenously under supervision at our institution, in

addition to the oral take-home doses. Prescriptions for stimulants, antidepressants, benzodiazepines, and neuroleptics during period 2 were also collected. Furthermore, the total number of antibiotic dispensing occurrences for each period was examined.

Gender and age data were collected from the electronic medical records. A manual review was conducted to identify emergency hospitalizations and detentions that occurred during the two observation periods. Emergency hospitalizations were categorized based on internal, surgical, and psychiatric treatments.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Diacetylmorphine (DAM)

Primary outcome(s)
Measured during the two time periods by retrospective chart review:
1. DAM dose
2. Number of antibiotic therapies
3. Number of emergency hospitalisations
4. Number of incarcerations

Key secondary outcome(s))
Measured during the two time periods by retrospective chart review:
1. Age
2. Gender
3. Additional daily medication
4. Injectable DAM

Completion date
31/05/2022

Eligibility

Key inclusion criteria
We included all patients that received oral DAM and were assessed to stable by their therapist and qualified accordingly for a prolonged take home of seven days. In addition, the patients had to have been on oral DAM since at least March 19th, 2019 with no treatment interruptions until March 18th, 2021.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

All

Sex
All

Total final enrolment
134

Key exclusion criteria
1. Only injectable DAM
2. Missing informed consent
3. Interruption of DAM during observation period

Date of first enrolment
15/06/2021

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
Switzerland

Study participating centre
Arud Centre for Addiction Medicine
Schützengasse 31
Zurich
Switzerland
8001

Sponsor information

Organisation
Arud Center for Addiction Medicine

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study are available upon request from Franciska Brezan via f.brezan@arud.ch.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/04/2024	03/05/2024	Yes	No