

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

<b>Submission date</b> 14/06/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/06/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/05/2024	<b>Condition category</b> Other	<input type="checkbox"/> 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**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
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**

Arud Centre for Addiction Medicine Zurich

# 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](mailto:f.brezan@arud.ch).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		21/04/2024	03/05/2024	Yes	No