# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Oct 2026

## Whole-Body Cryotherapy (WBC) for COVID-19 recovered patients having anosmia or severe hyposmia

## Protocol summary


**Study aim**

Demonstrating that repeated cold exposure would improve olfactory function. It was hypothesized that high-dose WBC (five 3-min long sessions of whole body crytotherapy over 1 week) would result in more benefits that low-dose WBC (two 3-min long sessions of whole body cryotherapy over 1 week).

**Design**

Pilot randomized controlled trial with a parallel group design of forty-five COVID-19 recovered patients with anosmia or severe hyposmia, enrolled between February 2021 and April 2021. Olfactory function was assessed before and after intervention for each participant.

**Settings and conduct**

WBC sessions were conducted at the Cryotherapy Center of Bezannes, France. The day before and the day following the assigned intervention, each participant was examined by a physician who evaluated their sense of smell.

**Participants/Inclusion and exclusion criteria**

Participants had to be COVID-19 recovered patients with residual anosmia or severe hyposmia after diagnosis of SARS-CoV-2 infection (positive PCR test). Participants with medical contraindications to Whole-Body Cryotherapy were excluded.

**Intervention groups**

There were two intervention groups and one control group. In the first intervention group (high-dose WBC) participants received daily sessions (5 days over one week) of WBC. Each session was 3 minutes in length and was performed in a cryotherapy chamber exposing individuals to freezing dry air at a temperature of -90°C. In the second intervention group (low-dose WBC), the intervention was similar but participants received only two WBC sessions over one week.

**Main outcome variables**

Our main outcome variable was participants' score change on a Visual Analog Scale. We used a straight horizontal line of 100 mm with "0" indicating no loss of the sense of smell compared to what it was before COVID-19 infection and "100" indicating complete loss.


## General information

**Reason for update**

**Acronym**

CRYOTAN

**IRCT registration information**

IRCT registration number: **IRCT20210708051817N1**
Registration date: **2021-07-14, 1400/04/23**
Registration timing: **retrospective**

Last update: **2021-07-14, 1400/04/23**
Update count: **0**

**Registration date**

2021-07-14, 1400/04/23

**Registrant information**


**Name**

Fabien LEGRAND

**Name of organization / entity**

University of Reims Champagne Ardenne

**Country**

France

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-02-01, 1399/11/13

**Expected recruitment end date**

2021-05-01, 1400/02/11

**Actual recruitment start date**

2021-02-15, 1399/11/27

**Actual recruitment end date**
2021-04-19, 1400/01/30
**Trial completion date**
2021-05-01, 1400/02/11

**Scientific title**
Whole-Body Cryotherapy (WBC) for COVID-19 recovered patients having anosmia or severe hyposmia

**Public title**
Whole Body Cryotherapy (WBC) for treating anosmia / hyposmia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
recovered COVID-19 patients (asymptomatic for at least 3 weeks) anosmia or severe hyposmia (more than 50 percent reduction of olfactory acuity)
**Exclusion criteria:**
medical contraindications to Whole-Body Cryotherapy
**Age**
From **18 years** old to **79 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **42**
Actual sample size reached: **45**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
A permutated block randomization design at the level of the individual was used, with a block size of three individuals. In each block of three, two patients were randomly assigned to the experimental groups (low-dose WBC, high-dose WBC) and one patient to the control group. This was done using sealed envelops. There was no allocation concealment.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of the Société Française de Cryothérapie Corps Entier
**Street address**
11 avenue du Tremblay
**City**
Paris
**Postal code**
75012 Paris
**Approval date**
2021-01-10, 1399/10/21
**Ethics committee reference number**
SFCCE-2021-3

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19 induced anosmia or severe hyposmia (defined as more than 50 percent of loss of sense of smell)
**ICD-10 code**
U07.1
**ICD-10 code description**
U07.1 COVID-19, virus identified

## Primary outcomes

### 1

**Description**
participant's score change on the Visual Analog Scale measuring the loss of sense of smell
**Timepoint**
the day before and the day following intervention
**Method of measurement**
participant's self-report evaluation on a Visual Analog Scale 0-100 ; with "0" indicating complete loss of sense of smell compared to what it was before being infected by COVID-19; and"100" indicating full recovery of sense of smell.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group 1: high-dose Whole-Body Cryotherapy (WBC). Participants receive daily sessions of WBC in a cryotherapy chamber at temperature of -90°C. Sessions are 3 minutes in length. Intervention's duration is 5 days.
**Category**
Treatment - Other

### 2

**Description**
Intervention group 2: low-dose Whole-Body Cryotherapy (WBC). Participants receive daily sessions of WBC in a cryotherapy chamber at temperature of -90°C. Sessions

are 3 minutes in length. Intervention's duration is 2 days.

**Category**
Treatment - Other

**3**

**Description**
Control group: participants in the control group received no WBC sessions

**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Cryotherapy Center "CRYOTERA"

**Full name of responsible person**
Bastien Bouchet

**Street address**
7 rue Jules Méline

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Bezannes

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51430

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bastien.bouchet@cryotera.fr

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
The University of Reims Champagne Ardenne

**Full name of responsible person**
Fabien Legrand

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**Grant name**
non pharmacological interventions

**Grant code / Reference number**
NPI-2021-2

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
The University of Reims Champagne Ardenne

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
The University of Reims Champagne Ardenne

**Full name of responsible person**
Fabien Legrand

**Position**
Assistant Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Health Promotion

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## Person responsible for scientific inquiries

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Professor

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
we will provide all collected deidentified participants' data set in a .xls file

**When the data will become available and for how long**
data set will be available as of 1 September 2021 for one full year

**To whom data/document is available**
data set will be available for people working in academic institutions

**Under which criteria data/document could be used**
data can be used for scientific purposes

**From where data/document is obtainable**
person to be contacted: fabien.legrand@univ-reims.fr

**What processes are involved for a request to access data/document**
write an email explaining what for you might need the data set

**Comments**