

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 cryotherapy over 1 week) would result in more benefits than 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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Email address

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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 permuted 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 envelopes. 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

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7 rue Jules Méline

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51430

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Email

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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9 Boulevard de la Paix

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Reims

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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**Contact****Name of organization / entity**

The University of Reims Champagne Ardenne

Full name of responsible person

Guillaume Polidori

Position

Professor

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Other areas of specialty/work

Health Technology Assessment

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Person responsible for updating data

Contact

Name of organization / entity

Société Française de Cryothérapie Corps Entier

Full name of responsible person

Bastien Bouchet

Position

Manager

Latest degree

Master

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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