Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Oct 2023

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

+33 3 26 91 38 90

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 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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+33 3 26 77 97 50

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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

Contact

Name of organization / entity
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Position
Professor

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Health Technology Assessment

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Person responsible for updating data

Contact

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Société Française de Cryothérapie Corps Entier

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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