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Can a new formulation of Botulinum Toxin Type A improve its efficiency over the wrinkles?

Submission date
03/07/2017

Recruitment status
No longer recruiting

Registration date
10/07/2017

Overall study status
Completed

Last Edited
30/11/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Botulinum toxin injections, also known as Botox or Dysport, are treatments that are injected to relax muscles. This is usually injected in to the face to improve the look of wrinkles. The botulinum toxin needs to be mixed with a saline to be reconstituted (restoring something dried by adding water or saline (salt water)). This can be done with different types of saline solutions, including sodium chloride or zinc gluconate. The aim of this study is to compare the effect of botulinum toxin treatments diluted with different compounds to see if they are effective.

Who can participate?
Females aged 50 and older who have not received botulinum toxin injections for the last six months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the treatment that is diluted with sodium chloride. Participants receive the treatment that is diluted with zinc gluconate. Participants receive a range from 8 to 25 units in their forehead. Participants are followed up two, four and 14 weeks after being treated to assess their wrinkles and quality of life.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in the wrinkles. There are risks of scratches, asymmetry, pain (at application), edema (swelling), ineffectiveness and ecchymosis.

Where is the study run from?
Pontifical Catholic University of Rio Grande do Sul (Brazil)

When is the study starting and how long is it expected to run for?
March 2014 to February 2018

Who is funding the study?
Investigator initiated and funded (Brazil)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0

Study information

Scientific Title
Incobotulinumtoxin diluted in zinc gluconate solution for facial wrinkles: randomized clinical trial

Study objectives
Null hypothesis:
The effect of injecting the diluted botulinum toxin in 0.9% sodium chloride physiological solution has the same duration as the injection of botulinum toxin diluted in 0.02% zinc gluconate in the frontal muscle.

Hypothesis:
The effect of injection of botulinum toxin diluted in 0.02% zinc gluconate has a longer duration than the injection of botulinum toxin diluted in saline solution only 0.9% sodium chloride in the frontal muscle.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of PUCRS, 09/12/2014, ref: 903.330

Study design
Prospective double-blind randomised longitudinal case/control study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
The sample consisted of 48 female participants, over 50 years of age and divided into two groups. The participants were submitted to botulinum toxin application in the upper third of the face, specifically in the frontal muscle, and in 24 participants the dilution of Botulinum Toxin was with 0.02% Zinc Gluconate Solution (Case Group) and 24 participants with dilution Of Botulinum Toxin in 0.9% Physiological Solution (Control Group).

Interventions
Participants are randomly allocated to either the control of the case group.

All participants receive doses ranging from 8 to 25 units in the frontal muscle, according to recommendations of application in this region.

Participants in the control group receive a toxin diluted in 0.9% sodium chloride in each spot.

Participants in the case group receive the treatment toxin diluted in 0.02% zinc gluconate.

Participants receive the treatment once and then receive follow up on week two, four and 14 to assess their wrinkles and quality of life.

Intervention Type
Other

Primary outcome measure
1. Wrinkle evaluation (on movement and at rest) is measured using the Merz Aesthetics scale at baseline, weeks two, four and 14
2. Quality of life is measured using the WHO Quality of Life score at baseline and week 14

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
02/03/2014

Completion date
07/02/2018

Eligibility

Key inclusion criteria
1. All female participants
2. 50 years of age or older
3. Agreed to the study and signed the informed consent form
4. No history of chronic gastrointestinal disease (diarrhea, inflammatory bowel disease or celiac disease) with frontal wrinkles
5. Muscle contraction (dynamic)
6. At least 6 months without receiving botulinum toxin application for any indication
7. Participants who were never submitted to this treatment

Participant type(s)
Other

Age group
Mixed

Sex
Female

Target number of participants
The sample consisted of 48 female participants, over 50 years of age and divided into two groups.

Key exclusion criteria
1. Individuals of the male gender
2. Female subjects under 50 years of age
3. Did not agree to the study and did not sign the informed consent form
4. History of chronic gastrointestinal disease (diarrhea, inflammatory bowel disease, or Celiac disease)
5. Diabetes mellitus
6. Lack of wrinkles to muscle contraction (dynamic or static)

7. Underwent botulinum toxin treatment for less than 6 months for any indication were not included in the study

Date of first enrolment
16/08/2017

Date of final enrolment
22/11/2017

Locations

Countries of recruitment
Brazil

Study participating centre
Pontifical Catholic University of Rio Grande do Sul
Ipiranga Avenue
6681 Partenon
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Sponsor information

Organisation
Pontifical Catholic University of Rio Grande do Sul (Pontifícia Universidade Católica do Rio Grande do Sul (PUCRS))

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Sponsor type
Other

Website
http://www.pucrs.br/igg-acad/

ROR
https://ror.org/025vmq686

Funder(s)

Funder type
Not defined

Funder Name
Investigator initated and funded

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date
31/08/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/09/2017	30/11/2021	Yes	No