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Effect of stem cells on hypoactive bladder

Submission date
13/03/2021

Recruitment status
No longer recruiting

Registration date
15/03/2021

Overall study status
Completed

Last Edited
05/04/2023

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
An underactive bladder (also known as detrusor hypocontractility or hypocontractile bladder) is a bladder which has a contraction of reduced strength and/or reduced duration, resulting in slow bladder emptying or an inability to completely empty. There are several causes for this condition, including old age, drugs, medical activity, neurogenic causes (stroke, multiple sclerosis, Parkinson's disease, spinal cord injury), obstruction, diabetes and infectious diseases of the nervous system (AIDS, syphilis and Guillan-Barre Syndrome). Programmed urination, double urination, al-blockers and occasional self-catheterization are typical conservative treatment options. The aim of this study is to evaluate the effect of mesenchymal stem cells in patients with detrusor hypocontractility.

Who can participate?
Patients with detrusor hypocontractility

What does the study involve?
Participants' peripheral fat is collected through liposuction on an outpatient basis. The material will be grown in a cell culture laboratory. After 60 days participants will receive two injections of stem cells at 30-day intervals. Patients will be evaluated before and after this intervention with a urodynamic study and a questionnaire.

What are the possible benefits and risks of participating?
All treatments will produce some improvement in the health of individuals with better bladder functioning and relief of symptoms, providing better quality of life. There are risks related to the procedures used in this research.
Urodynamic evaluation has a low risk of complications as it will be performed by a single evaluator, doctor, urologist, with 10 years of experience in the area. The materials used will all be disposable and for single use. All principles of aseptic technique will be respected to avoid any infection. The patient will be evaluated and assisted by the outpatient medical and nursing staff during and after the procedure to detect and treat any complications such as pain and urinary tract infection.
Risks related to the collection of fat include small bleeds generating bruises, as well as infection, bruising on the skin, pain and rocky spots on the skin.
Lidocaine used during fat collection can cause a hypersensitivity reaction (allergy). For this reason, the patient will be assisted by the medical and nursing staff before, during and after the

procedure through continuous monitoring of their vital signs.
The stem cell injection technique will be performed by a trained medical professional in a proper environment that guarantees maximum hygiene and safety. The application technique will be cystoscopy (endoscopy of the urinary tract with a local anesthetic using 2% lidocaine gel). The materials used will all be sterilized with standard methods such as ethylene oxide. Disposable and single-use materials as determined by the standard aseptic technique. Patients will receive standard antibiotic prophylaxis. The complications that can occur during cystoscopy are pain, bleeding, urinary tract infection and discomfort to urinate after the procedure. Patients will be evaluated and monitored by medical and nursing staff before, during and after the procedure and will receive all necessary treatment and comforts.
Regarding the use of stem cells, there is a risk in patients with malignant diseases. Therefore, this clinical condition (history of cancer) will be an exclusion criterion to be considered.
The use of mesenchymal stem cells in research to treat other diseases has not identified significant adverse effects except for transient fever, nausea, diarrhea, headache and abdominal pain, bloating, and dizziness, among others.
All phases of the project will be monitored and patients will receive all the necessary guidance and care to minimize risks and treat any complications resulting from treatment. Participants will be informed of the risks and benefits of the research, they will have access to data and medical records according to the medical code of ethics. The University Hospital structure will also be available for outpatient treatment, tests and hospitalization that are necessary under the supervision of this researcher, as well as direct access via personal phone.

Where is the study run from?
University Hospital of the Federal University of Mato Grosso do Sul (Brazil)

When is the study starting and how long is it expected to run for?
July 2017 to April 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
78716517400000021

Study information

Scientific Title
Effect of mesenchymal stem cells in patients with detrusor hypocontractility

Acronym
EMSCPWDH

Study objectives
To evaluate the effect of mesenchymal stem cells in patients with detrusor hypocontractility.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/07/2018, national research ethics committee (SRNTV 701, Via W 5 Norte – Edificio PO700, 3° Andar, Asa Norte, Brasilia – DF, Brazil, 70719-049; +55 (0)61 33155877; conep@saude.gov.br), ref: CAAE 78716517.4.0000.0021

Study design
Open clinical test

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Detrusor hypoactivity (underactive bladder)

Interventions
Patients will be selected in the urology service of the University Hospital with a diagnosis of detrusor hypoactivity. 10 patients will be selected and invited to sign the informed consent form. These patients will be subjected to the collection of peripheral fat through liposuction on an outpatient basis. The material will be grown in a cell culture laboratory. After 60 days they will receive two intravesical injections of stem cells at 30-day intervals. Patients will be evaluated before and after this intervention with a urodynamic study and an ICIQ-SF questionnaire.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome measure
Bladder function will be assessed through urodynamic study before the patient is subjected to fat collection and 60 days after the second stem cell transplant

Secondary outcome measures
The quality of life of patients with urinary incontinence secondary to this voiding dysfunction, assessed using the international continence on incontinence questionnaire – short form (ICIQ-SF) before and 60 days after the second stem cell transplant

Overall study start date
01/07/2017

Completion date
01/04/2021

Eligibility

Key inclusion criteria
1. Male and female patients with a urodynamic study showing only detrusor hypocontractility, without the presence of an obstructive factor to urinary flow
2. On a clean intermittent catheterization regime
3. Not undergoing any surgical procedure in the lower urinary tract in the last 12 months

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
10

Total final enrolment
9

Key exclusion criteria
1. End-stage renal failure (with oligo-anuria)
2. Recurrent urinary tract infection
3. Non-adherence to clinical monitoring protocols and clean intermittent auto-catheterization
4. Presence of any malignant neoplasm confirmed in treatment or recently treated or even any suspicion of cancer will be an important exclusion criterion due to contraindication to the use of stem cells in these patients

Date of first enrolment
01/10/2019

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
Brazil

Study participating centre
Universidade Federal de Mato Grosso do Sul
Rua Senador Fillinto Muller 355
Campo Grande
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Sponsor information

Organisation
Federal University of Mato Grosso do Sul

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Sponsor type
University/education

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ROR
https://ror.org/0366d2847

Funder(s)

Funder type
Other

Funder Name
Investigator initated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2021

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
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/04/2023	05/04/2023	Yes	No