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Stem cell transplantation in human testis for the treatment of male infertility

Submission date	Recruitment status	[_] Prospectively registered
05/01/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
27/02/2009	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Zaid Kilani

Contact details
The Farah Hospital
May Ziadeh Street
P.O. Box 5323
Jabal
4th circle
Amman
Jordan
11183
+962 6 460 3555
farah1@go.com.jo

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Bone marrow stem cell transplantation in human testis for men with sever oligospermia or azospermia: a pilot study

Study objectives
Testes have two main functions in mammals: to produce androgens and spermatogenesis which occurs in the seminiferous tubules. Spermatogonial stem cells are undifferentiated cells defined by their ability to both self-renew and differentiate into mature spermatozoa. Bone marrow stem cells (BMS cells) have been shown to be able to transdifferentiate to male germ cell-like cells. In male mice, a recent study has demonstrated that bone marrow stem cells are able to differentiate into primordial germ cells and spermatogonia both in vitro and in vivo.

In a more recent study, adult bone marrow cells injected into seminiferous tubules or interstitial spaces were not only able to differentiate into germ cells (spermatogonia and spermatocytes) but as well as Sertoli and Leydig cells. This finding may be of clinical relevance to unique treatment of male infertility. The ability to derive male germ cells from BMS cells opens the possibilities for use of these cells in reproductive medicine mainly male infertility. In order to encourage BMS cells to differentiate into germ cells, the isolated cells should be cultured in a medium very similar to that found in the testes. Thus, Obtaining BMS cells from the infertile man and injecting it - after preparation - into the seminefrous tubules or around it may stimulate its differentiation into germ cells.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Farah Hospital Ethical Committee, approved on 13/12/2008 (ref: 1).

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Male infertility and spermatogenesis

Interventions
Forty men with sever oligospermia and 20 men with azospermia will be recruited (total: 60 participants).

Participants will be randomised to have BMS cells transplantation or no therapy. In the oligospermia group, 20 cases will receive BMS cells and in the azospermia group, only 10 will receive it. Randomisation ratio will be 1:1.

For safety of participants, BMS cells will be injected in one testis only and the other testis will be spared.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Laboratory safety: White Cell Count (WCC) and platelet count, assessed once per month for three month
2. In azospermia group: Histopathology of evidence of differentiation. Testicular biopsy will be obtained after three month of injection.
3. In oligospermia group: Significant increase in number of sperms on three successive semen samples, assessed after 1, 2 and 3 months of injection

All primary outcome measures will be followed up for 180 days.

Secondary outcome measures
1. Sperm activity and ability to fertilise oocyte, assessed each time sperm is obtained throughout the study
2. Pregnancy rate within one year of injection
3. Miscarriage rate within one year of injection
4. Long term follow-up for any adverse effect, assessed for one year from injection

All secondary outcome measures will be followed-up for one year.

Overall study start date
15/01/2009

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Men with idiopathic severe oligospermia defined as less than one million sperm per ml, or men with azospermia

2. Men between 20-50 years old
3. Normal serum levels of gonadotropines, testosterone and prolactine
4. Absence of infectious genital disease and anatomical abnormalities of the genital tract
5. Absence of smoking, drug addiction or alcohol consumption

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
60

Key exclusion criteria
1. Men with previous surgery in testis
2. Those with major medical problem such as malignancy, hepatitis, etc.

Date of first enrolment
15/01/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Jordan

Study participating centre
The Farah Hospital
Amman
Jordan
11183

Sponsor information

Organisation
The Farah Hospital (Jordan)

Sponsor details

May Ziadeh Street
P.O. Box 5323
Jabal
4th circle
Amman
Jordan
11183
+962 6 460 3555
farah1@go.com.jo

Sponsor type
Hospital/treatment centre

Website
http://www.farah-hospital.org/

ROR
https://ror.org/02qnzpb65

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Farah Hospital (Jordan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration