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Immune response and pathogen-fertility

Submission date	Recruitment status	[_] Prospectively registered
27/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/05/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/05/2020	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Candida albicans is a type of yeast (fungus) naturally found in small amounts in the human body. Candidiasis is a fungal infection caused by the overgrowth of this yeast. Candidiasis can occur in almost any part of the body, and anyone can develop it. However, certain groups of people are more at risk. These include the elderly, critically ill people, people with weakened immune systems and some medicines. It is thought that Candidiasis has an impact on both male and female infertility, but this is not fully understood. While the role of fungal infections and Th17-related diseases in female infertility has been documented, the vast majority of the studies have used rats and mice as subjects; whether or not the results would be the same for humans is not known. A particular subset of immune cells (Th17 cells) ensures a robust anti-fungal response in healthy people. The aim of our study is to characterise the immune response (Th17) by both fertile and infertile couples (men and women).

Who can participate?
Healthy participants and patients who are under investigation for fertility problems.

What does the study involve?
White (mononuclear) blood cells from fertile and infertile couples are tested for production of the cytokine IL-17 (hallmark cytokine of the anti-fungal Th17 response) after in vitro stimulation with Candida. The samples (saliva, vaginal swab and semen) are also tested for Candida colonization.

What are the possible benefits and risks of participating?
Participants will benefit in terms of prevention, identification of high risk for development of Candida infection, in particular, for participants without symptoms, the potential for reproductive complications and treatment. The identification of additional specific risk factors in women and/or their partners might aid their fertility treatment and this is one expected outcome of the proposed study.

Where is the study run from?
Abertawe Bro Morgannwg University Health Board NHS Wales (UK)

When is the study starting and how long is it expected to run for?
March 2015 to June 2021

Who is funding the study?
Abertawe Bro Morgannwg University Health Board NHS Wales (UK)

Who is the main contact?
Dr Nadja Melo

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Immune Response and the Pathogen-Female & male fertility interface

Acronym
IRPF study

Study objectives
To characterise the anti-fungal host response (Th17) by fertile and infertile women and men

Ethics approval required
Old ethics approval format

Ethics approval(s)

HRA NRES, 05/02/2015, ref: 15/LO/0258

Study design
Observational, single-centre, cross-sectional study.

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
The objective of our study is to characterise the anti-fungal host response (Th17) by fertile and infertile (women and men) couples.

Interventions
Blood mononuclear cells from fertile and infertile couples will be tested for production of the cytokine IL-17 (hallmark cytokine of the anti-fungal Th17 response) after in vitro stimulation with Candida. The samples (saliva, vaginal swab and semen) also will be assessed for Candida colonization.

Intervention Type
Procedure/Surgery

Primary outcome measure
Immune response of infertile patients will be evaluated by production of the cytokine IL-17 (hallmark cytokine of the anti-fungal Th17 response) after in vitro stimulation with Candida.

Secondary outcome measures
The samples (saliva, vaginal swab and semen) also will be assessed for Candida colonization.

Overall study start date
12/03/2015

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Healthy patients without fertility problem
2. Patients who are under fertility investigation

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Pregnant patients
2. Patients diagnosed with HIV or hepatitis
3. Intravenous drug users
4. Individuals unable to provide informed consent
5. Those who have participated in clinical research in the last 6 months

Date of first enrolment
01/04/2015

Date of final enrolment
12/03/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
ABM UHB NHS Wales UK
United Kingdom
SA12 7BR

Sponsor information

Organisation
ABM UHB NHS Wales UK

Sponsor details
Abertawe Bro Morgannwg University Health Board /Morriston Hospital
Swansea

Wales
United Kingdom
SA6 6NL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Abertawe Bro Morgannwg University Health Board NHS Wales

Results and Publications

Publication and dissemination plan
We intend to submit our results in the Immunology and Reproduction Journals around 2017.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No