

Immune response and pathogen-fertility

Submission date 27/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/05/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/05/2020	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

Study type(s)

Screening

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

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

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