# 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

Dr Nadja Melo

#### **ORCID ID**

https://orcid.org/0000-0003-4305-8395

#### Contact details

SWARU Singleton Hospital Swansea Sketty Lane Swansea United Kingdom SA2 8OA

# Additional identifiers

#### Protocol serial number

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

## 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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?HRA research summary28/06/2023NoNo