

The presence of *Candida albicans* in breastmilk during the breastfeeding period

Submission date 14/11/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/11/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/07/2018	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Breast pain during the breastfeeding period can affect mothers' self-confidence and her motivation to continue breastfeeding. Earlier research has not given any clear answers as to whether *Candida Albicans*, otherwise known as "thrush", can be the cause of breast pain. Different studies have shown varying results regarding the presence of *Candida Albicans* in breast milk. The aim of the present study is to examine whether women with symptoms that sound like they are related to thrush in the breast (cases) more often have *Candida Albicans* in their breast milk than women without these symptoms (controls). The study will examine whether women with breast pain more often cease breastfeeding than women without symptoms and whether the two groups show any difference in their confidence to breastfeed.

Who can participate?

Adult breastfeeding women over 18 years of age with and without breast pain.

What does the study involve?

All participants have samples of breast milk collected at the start of the study, which is then tested for the presence of the yeast *Candida Albicans*. Participants are also asked to complete a questionnaire to measure their self-confidence in breast feeding. One month later, participants are interviewed in order to find out whether they have continued breastfeeding.

What are the possible benefits and risks of participating?

There are no benefits or risks to individual women who choose to participate.

Where is the study run from?

Helsingborg Hospital (Sweden)

When is the study starting and how long is it expected to run for?

January 2014 to June 2017

Who is funding the study?

1. Stig & Ragnar Gorthon Foundation (Sweden)
2. The Milk Drop Foundation (Sweden)
3. Lions Research Foundation (Sweden)

Who is the main contact?

1. Miss Kirsti Kaski (public)
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Type(s)

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Additional identifiers

Protocol serial number

2014/600

Study information

Scientific Title

A case/control study of breastfeeding women with and without symptoms that are anecdotally related to thrush in the breast. Cases and controls will be compared for presence of *Candida albicans* in their breast milk, premature cessation of breastfeeding and confidence in their ability to breastfeed

Study objectives

Candida albicans is present in the milk of breastfeeding women who report breast pain to a higher degree than women without breast pain

Ethics approval required

Old ethics approval format

Ethics approval(s)

Central Ethical Review Board, Lund, Sweden, 16/09/2014 ref: 2014/600

Primary study design

Observational

Study design

Observational case-control study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Candidosis of the breast during breastfeeding

Interventions

Participants in the case group are informed about the study when they contact the breastfeeding clinic by telephone for symptoms associated with "thrush" infection in the breasts. Participants in the control group get information about the study and are recruited at local baby-well clinics while they have the routine health control.

One consult appointment occasion with a breastfeeding consultant is booked for the participants in the case group, inclusive usual consult appointment according the breastfeeding clinic routine.

Participants in the case group are recruited at the breastfeeding clinic after receiving more information and given a written consent. A questionnaire is used to collect information about age, parity, age of the breastfed baby, history of previous candida infections, Diabetes (gestational or type 1), type of delivery, antibiotic treatment during and after delivery, breastfeeding level (exclusive/non-exclusive), pain location and severity (NAS) and breastfeeding efficacy. Breastmilk from the most painful breast is collected for culture for *Candida albicans*.

Participants in the control group meet the researcher once at the baby-well clinic direct after a health control. They receive more information about the study and give their written consent. The same questionnaire as with the cases is used and breastmilk is collected for culture for *Candida albicans*.

Participants in the case group receive four weekly telephone contacts from a breastfeeding consult in the breastfeeding clinic. A questionnaire is used to collect information about pain severity (NAS), breastfeeding success, changes in symptoms and medicine therapy. After four weeks of telephone contacts they receive a mail questionnaire with same questions monthly in three months.

The controls receive a mail questionnaire monthly in four months with questions about breastfeeding success and if they have had symptom or pain associated with thrush in the breasts.

Intervention Type

Other

Primary outcome(s)

Presence of *Candida albicans* in breastmilk is measured using cultivation with Sabourad Agar or CROME Agar *Candida* at baseline

Key secondary outcome(s)

1. Breastfeeding efficacy in the breastfeeding mothers is measured by a validated breastfeeding instrument Breastfeeding Self Efficacy Scale- Short Form (BSES-SF) at baseline
2. Level of breastfeeding is measured by a questionnaire one month after the first contact with the researcher

Completion date

01/06/2017

Eligibility

Key inclusion criteria

Inclusion criteria for cases:

1. Breastfeeding woman
2. Adult, ≥ 18 years
3. Exclusive or non-exclusive breastfeeding
4. Good understanding of Swedish language in spoken and written form
5. One or several symptoms on the nipple and areola or in the breast: red, extenuated, tender, burning, sloughing skin on the nipple and areola, with or without deep, radiating, cutting pain sensations in the breast

Inclusion criteria for the controls:

1. Breastfeeding woman
2. Adult, ≥ 18 years
3. Exclusive or non-exclusive breastfeeding
4. Good understanding of Swedish language in spoken and written form
5. None of the symptoms on the nipple and areola or in the breast: red, extenuated, tender, burning, sloughing skin on the areola, with or without deep, radiating, cutting pain sensations in the breast

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Breastfeeding women with pain, skin symptoms or sores which can be attributed to breastfeeding technical difficulties such as short frenulum, mastitis or Raynaud's syndrome
2. Women with excema-like skin conditions and white spot

Date of first enrolment

01/04/2015

Date of final enrolment

01/03/2017

Locations**Countries of recruitment**

Sweden

Study participating centre

Helsingborg Hospital

Södra Vallgatan 5

Hlsingborg

Sweden

25187

Sponsor information**Organisation**

Stig & Ragna Gorthon Foundation

Organisation

Lions Research Foundation, Skåne

Organisation

Mjölkdroppen Association

Organisation

Gorthonstiftelsen

ROR

<https://ror.org/0192sgm30>

Funder(s)

Funder type

Charity

Funder Name

Stig & Ragna Gorthon Foundation

Funder Name

Lions Research Foundation

Funder Name

Mjölkdroppen Association

Results and Publications

Individual participant data (IPD) sharing plan

The data is expected to be available after the analysis of the data has been finished.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/06/2018		Yes	No

Participant information sheet	11/11/2014	30/11/2016	No	Yes
Participant information sheet	11/11/2014	30/11/2016	No	Yes