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The presence of Candida albicans in breastmilk during the breastfeeding period

Submission date
14/11/2016

Recruitment status
No longer recruiting

Registration date
30/11/2016

Overall study status
Completed

Last Edited
09/07/2018

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Community

Study type(s)
Diagnostic

Participant information sheet
See additional files (available in Swedish)

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

Secondary outcome measures
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

Overall study start date
01/01/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
35 participants in each study group.

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
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Sponsor information

Organisation
Stig & Ragna Gorthon Foundation

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Sponsor type
Other

Website
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Organisation
Lions Research Foundation, Skåne

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236 41
+46 (0)4045 78 52
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Sponsor type
Charity

Website
http://www.lffs.se

Organisation
Mjölkdroppen Association

Sponsor details
Södra Vallgatan 5
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Sweden
25187

Sponsor type
Charity

Organisation
Gorthonstiftelsen

Sponsor details

Sponsor type
Not defined

Website
https://www.gorthonstiftelsen.se/

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2017

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?
Participant information sheet		11/11/2014	30/11/2016	No	Yes
Participant information sheet		11/11/2014	30/11/2016	No	Yes
Results article	results	07/06/2018		Yes	No