Interventions for suppression of puerperal lactation

(protocol for systematic review)

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Background

- Suppression of lactation is essential in certain circumstances e.g. when breastfeeding is
  - *no longer required*
  - *inconvenient*
  - *risky for the newborn*

  Risk of HIV transmission through breastfeeding=16.2% (Nduati *et al* 2000)
- Over 30% of women in US and UK do not breastfeed their babies at all (Ryan 2002, Hamlyn 2002)

Background (contd)

- Cessation of lactation is associated with moderate to severe breast engorgement and pain in 2/3 of women when no treatment is given (Spitz et al 1998)
- Could lead to mastitis
- Breast engorgement is responsible for puerperal fever in 13.3% of non-breastfeeding mothers (Almeida 1986)

Available interventions

- Nonpharmacologic methods
- Breast binding/strapping, emptying of the breast, fluid restriction, application of external products e.g. belladonna ointment, cabbage leaves, ice packs, jasmine flower
- Data on efficacy are few and inconclusive

Pharmacologic methods

- Estrogen alone or in combination with androgen and/or progestogens
- Dopaminergic drugs (bromocriptine, cabergoline, lisuride)
- Antiserotonergic drugs (cyproheptadine, methysergide and metergoline)
- Clomiphene, pyridoxine, prostaglandin E2, frusemide, 2-mercaptopropionyl-glycine

Objectives

- To evaluate the effectiveness and safety of interventions used for suppression of lactation in puerperal women to determine which approach has the greatest comparative benefits with least risk

Criteria for considering studies

- Type of study: RCT evaluating the effectiveness of interventions used for suppression of puerperal lactation
- Type of participants: Puerperal women with indication(s) for suppression of lactation irrespective of parity (excluding those who deliver at less than 34 weeks)

Interventions

- Comparisons to be made will include:
  - Any intervention (nonpharmacologic or drug) versus no treatment or placebo
  - Nonpharmacologic versus drug treatment
  - Comparison of two different nonpharmacologic methods
  - Comparison of two different drug treatments
  - Comparison of two different drug combinations
  - Comparison of different doses of the same agent

Outcome measures

- **Primary**:

  (1) Failure to achieve suppression as described by (breast pain, engorgement, and milk secretion) on day 5 postpartum.

  (2) Adverse effects: Minor: nausea, vomiting, headache, dizziness; Major: thrombo-embolism, myocardial infarction, maternal death.

  (3) Acceptability of the intervention to the woman.

Outcome measures (contd)

- **Secondary**

  (1) Rebound lactation (as defined by authors of trials).

  (2) Time to achievement of complete inhibition of lactation.

  (3) Failure rate at two weeks (14 days).

  (4) Use of second line drug/method to achieve lactation suppression.

  (5) Secondary use of analgesics (mild or strong) to relieve symptoms.

Search strategy

- Search phrases: *lactation suppression*, *lactation inhibition*, *lactation prevention*, *stopping lactation and lactation*, *breastfeeding prevention*
- Cochrane Pregnancy and Childbirth Group Trials Register,
- MEDLINE (1966 till date), OLDMEDLINE (pre-1966), EMBASE (1974 till date), POPLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), MIDIRS (www.midirs.org), SIGLE (System on Information on Grey Literature), Conference Papers index (records of Conference presentation), MetaRegisters of Current Controlled Trials (http://controlled-trials.com and www.ncbi.nih.gov/clinical_trials).
- No language restriction

Method of review

- Screening of titles and abstracts
- Independent assessment of methodologic quality by two reviewers
- Data: setting, age, parity, indication
- No masking of authors or journals
- Quality evaluation: randomisation; allocation concealment; loss-to-follow-up; intention-to-treat
- Analysis with RevMan software
- Meta-analysis (if possible)

Subgroup analyses

- Any intervention vs no treatment or placebo
- Nonpharm. methods vs drug treatment
- Nonpharm. vs nonpharm
- Drug treatment vs drug treatment

Conflict of interest

- None

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