PRESENCE OF THE PARTNER IN THE OPERATING ROOM

During hyperacute cesarean section in general anesthesia

Statistical analysis plan

According to Gamble, Krishan, Stocken et al: Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA 2017;318(23):2337-2343

NA: not applicable

Concerning the protocol: NCT04948892

This Statistical Analysis Plan was finalized March 1st 2022.

Section 1: Administrative information

1a: The title of the project is "Presence of the partner in the operating room during hyperacute cesarean section in general anesthesia" (in Danish: Sectio grad 1. Partneren med på operationsstuen?)

1b: The trial protocol is registered at clinicaltrials.gov (NCT04948892). Since there is no intervention in the trial, approval from the Research Ethics Committee was not required. The trial is approved by the Research Ethis Committee of the University of Southern Denmark (approval 21/62092, November 19., 2021). The study is approved by the Data Management authority of the Region of Southern Denmark (file number 21/56789, October 25., 2021).

2: SAP version 1.1

3: Referring to the trial protocol per November 1st, 2021.

4: NA

5: The statistical analysis plan is developed by:

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And approved by the rest of the trial investigators.

Section 2: Introduction

7: Synopsis of trial background and rationale

This study concerns cesarean sections, category 1, meaning those cases where the life of mother and/or fetus is in immediate danger and the child must be delivered within 15 minutes from activating the cesarean section team. In most hospitals in Denmark, these cesarean sections are most often performed in general anesthesia and the mother is endotracheally intubated.

Previously in these situations, as the mother was rushed from the Labour Ward to the operation room (OR), her spouse/partner, would be placed outside the OR, and would stay there until the child had been delivered.

In Lillebaelt Hospital, Kolding, Denmark, the newborn-resuscitation table is placed inside the OR. The partner would most often be allowed to enter the OR when the child was delivered and placed on the resuscitation table (no matter the status of the child). However, during 2021, Lillebaelt Hospital Kolding updated the policy regarding the handling of the partner during cesarean section category 1 (implemented in the local guideline December 2021). Now the partner is present in the OR during the whole procedure, including the induction of general anesthesia, endotracheal intubation, performing the cesarean section (drapings are positioned so that the partner cannot see the operation field) and potential resuscitation efforts of the newborn.

In another hospital in the same region (Region of Southern Denmark), Aabenraa Hospital, the partner is not present in the OR during the cesarean section category 1. The partner waits in the labour ward.

The investigators therefore wish to investigate how the cesarean section category 1 is experienced by: the partner; the mother; the obstetrician; the anesthesiologist; the midwife; the OR nurse; the anesthetic nurse, both in Kolding where the partner is present in the OR, and in Aabenraa, where the partner is not present in the OR during the cesarean sectio.

In 2020 there were 16 cesarean sections category 1 in Kolding and 15 in Aabenraa.

8: Description of specific objectives or hypotheses

We hypothesize the mothers and partners will prefer the partner being present in the OR during the cesarean section category 1.

Sectio 3: Study methods

9: Trial design: This is prospective cohort trial with two parallel cohorts in two centers (Kolding and Aabenraa).

10: Randomization: This is a non-randomized trial.

11: Sample size: The trial is based on a convenience sample consisting of all the cesarean sections in 2022 in each of the two participating centers.

12: Framework: This is an exploratory trial without statistical power to perform superiority, equivalence, or noninferiority hypothesis testing.

13: Statistical interim analyses: NA

14: Timing of final analysis: All analyses will be conducted when the inclusion period has ended (January 1st 2023).

15: Timing of outcome assessments: outcomes will be assessed for each cesarean section (first questionnaire in day 1 or 2 following the cesarean section, follow-up interview three months later). Data on outcomes will be analyzed when the inclusion period has ended.

Section 4: Statistical Principles

16: Level of statistical significance: a p-value of <0.05 will be considered significant. However, due to the expected low number of cases (expected approx. 15 cesarean section category 1/year in each center), it is likely that descriptive statistics will be most appropriate.

17: Description and rationale for any adjustment for multiplicity: NA

18: Confidence intervals to be reported: see 16.

19a: Definition of adherence to the intervention: for each cesarean section is will be described whether or not the partner was present in the operation room during the cesarean section.

19b: Description of how adherence to the intervention will be presented: the information will be available in the result section in the final manuscript.

19c: Definition of protocol deviations for the trial: for various reasons the partner may or may not be present in the OR even though he/she was supposed to or supposed not to; there might not be a partner, the partner could be ill or otherwise occupied etc.

19d: Description of which protocol deviations will be summarized: in tabular form in the result section in the final manuscript.

20: Definition of analysis populations, eg, intention to treat, per protocol, complete case, safety: We will perform intention-to-treat analyses. However, as the trial aims to explore the situation of having the partner present in the OR versus not having the partner present, we will also assess data per protocol, if it turns out that there are multiple cases of protocol deviations. This will be done using descriptive statistics, and without statistical tests.

Section 5: Trial Population

21: Screening data: We have not collected screening data but planned for a convenience sample of one year inclusion period.

22: Summary of eligibility criteria: All cesarean section category 1 in 2022 are eligible and mother and partners will be approached for consent to participate.

23: Information to be included in the CONSORT flow diagram: see template for Consort flow diagram for the trial.

24a: Level of withdrawal, eg, from intervention and/or from follow-up: We expect that 20% of the mothers and partners will decline to participate. We expect that >90% of partners, who accept to participate, will also participate in the follow-up interview.

24b: Timing of withdrawal/lost to follow-up data: NA

24c: Reasons and details of how withdrawal/lost to follow-up data will be presented: Data will be presented in the result section of the final manuscript.

25a and b: Baseline patient characteristics:

Table 1. Baseline data

	Kolding n=	Aabenraa n=
Age of mother		
BMI, mother		
ASA score, mother		
Parity, mother		
Partner was present during cesarean section		
Age of partner		
Indication for cesarean section -fetal distress -bleeding -uterus rupture -other		
Time from calling the cesarean section till infant is delivered		
Bleeding, ml		
Need for blood transfusion		
APGAR scores -1 min -5 min -10 min		
Surgical complications -bladder perforation -bowel perforation -bleeding>1000 ml		
Anestesiological complications -difficult airway -esophageal intubation -aspiration		
Time from cesarean section to discharge from hospital		
Postoperative infection		
Need for repeat surgery		
Additional clinically relevant information from each cesarean section		

Section 6: Analysis

26: Outcome definitions

The primary outome will be the partners answer to the main study question: “Would you have preferred to wait outside the OR during the anesthesia and cesarean section?” for partners in Kolding and “Would you have preferred to be present in the OR during the anesthesia and cesarean section?” for partners in Aabenraa. This question is asked both at first interview (day 1 or 2 following the cesarean section) and at follow-up three months later. The number of partners answering “yes” will be shown in number and percentages, n (%).

Secondary outcomes will be narrative and tabular descriptions of questionnaire data from mothers, medical data regarding the cesarean section and infant, follow-up interviews and questionnaires from health care professionals.

27: Analysis methods: Descriptive statistics will be used where appropriate.

As cesarean section category 1 is usually performed by a smaller group of specialized clinicians, it is likely that the same clinicians will perform several of the cesarean sections in this study. As part of the analyses, data will be investigated for clinician-specific effects by including the clinician as a random effect in a mixed effect model and investigate the varians components. If there should be clinicial specific effects, against what we expect, the statistical analyses will include the found cluster structure and analyse as non-independent data.

28: Missing data: We will present the extent of missing data. No form of imputations for missing data will be used.

29: Additional analyses: None planned.

30: Harms: NA, as this is an observational study, describing the existing practice in two different hospitals.

31: Statistical software: STATA will be used.