TRACE II Prospective study: Outcome in patients undergoing postponed elective surgery during the COVID-19 pandemic

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24690

Source
Nationaal Trial Register

Brief title
TRACE II Prospective

Health condition

Surgery patients

Sponsors and support

Primary sponsor: MUMC+
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

- 30-day incidence of major (Clavien-dindo classification III, IV and V) postoperative complications (including mortality)

Secondary outcome

- 30-day incidence of minor (Clavien-dindo classification I and II) postoperative complications
- length of stay (LOS) (hospital, medium care, intensive care)
- one-year mortality
- 30-day and one-year quality of life

Study description

Background summary

We aim to prospectively follow surgical patients during the upscaling phase in Dutch hospitals, and compare this new cohort with the control cohort from the TRACE study.

Study objective

We hypothesize that surgical patients in the new cohort have poorer health conditions prior to surgery and poorer health outcomes post-surgically compared to the control cohort (TRACE study)

Study design

Pre-operative, intra-operative, post-operative, 30 day and 1 year post-operatively

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

All adult (18 years and older) patients undergoing elective surgery, with an indication for postoperative hospital stay, and meeting at least one of the following criteria:
- indication of postoperative pain therapy with follow up by Acute Pain Service
- ≥60 years
- ≥45 years and a revised Cardiac Risk Index (rCRI) > 2
- surgical APGAR score (sAPGAR) <5 (patients not fulfilling this and any other criterion will be excluded after surgery)

Exclusion criteria

- Patients who do not sign informed consent
- Patients who are not able to complete the questionnaires in the Dutch language
- Pregnancy and caesarean sectio
- Fractures, appendectomy, organ transplant (donor)
- Screening failures: Patients who completed both questions “Was uw operatie uitgesteld tijdens de coronacrisis?” and “Denkt u dat het inplannen van uw operatie vertraging heeft opgelopen tijdens de coronacrisis?” with “No”.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2020

Enrollment:	2500
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
After the study, data will be standardized (SNOMED coding), and datasets and metadata will be made available via a public repository

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8841
Other	METC Amsterdam UMC, location AMC : W20_384 # 20.429 (reference non-WMO confirmation)

Study results

Summary results
Scientific results will be presented in scientific papers, and submitted for publication in

international open access journals