Impact of Semi-automated proposal and optimization of diagnoses and surgical procedures for precoding: a randomized controlled trial

Study Type:	Other Clinical Trial according to ClinO, Chapter 4
Risk Categorization:	Not applicable
Study Registration:	Intended registry: clinicaltrials.gov Intended Registration: FOPH portal SNCTP (Swiss National Clinical Trial Portal)
Sponsor/Investigator	Dr. Thomas Steffen Department of Surgery Kantonsspital St. Gallen, St. Gallen, Switzerland E-mail: Thomas.Steffen@kssg.ch Phone: +41714941314
Investigated Intervention:	Daily monitoring and optimization of DRG coding
Protocol ID	Not applicable
Version and Date:	Version 2 (dated 24/05/2019)

PROTOCOL SIGNATURE FORM

Study Title	Impact of Semi-automated proposal and optimization of diagnoses and surgical procedures for precoding: a randomized controlled trial
Study ID	Not applicable

The Sponsor-Investigator has approved the protocol version 2 (dated 24/05/2) and confirm hereby to conduct the study according to the protocol, current version of the World Medical Association Declaration of Helsinki, and ICH-GCP guidelines as well as the local legally applicable requirements.

Sponsor-Investigator:

Name: *Dr. Thomas Steffen*

Date: _____ Signature: _____

Co-Investigator:

Name: PD *Dr. Ignazio Tarantino*

Date: _____ Signature: _____

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GLOSSARY OF ABBREVATIONS

AE	*Adverse Event*
ASR/DSUR	*Annual Safety Repot / Development Safety Report*
BASEC	*Business Administration System for Ethical Committees*
CRF	*Case Report Form*
CTCAE	*Common Terminology Criteria for Adverse Events*
FADP	*Federal Act on Data Protection (in German: DSG, in French: LPD, in Italian: LPD)*
eCRF	*electronic Case Report Form*
FOPH	*Federal Office of Public Health*
GCP	*Good Clinical Practice*
HRA	*Human Research Act (in German: HFG, in French: LRH, in Italian: LRUm)*
ICH	*International Conference on Harmonisation*
ClinO	*Ordinance on Clinical Trials in Human Research (in German: KlinV, in French: OClin, in Italian: OSRUm)*
SAE	*Serious Adverse Event*

1 STUDY SYNOPSIS

Sponsor / Sponsor-Investigator	Name(s) and contact details of Sponsor / Sponsor-Investigator
Study Title	Impact of Semi-automated proposal and optimization of diagnoses and surgical procedures for precoding: a randomized controlled trial
Short Title / Study ID	Semi-automated Precoding
Protocol Version and Date	Version 2 (dated 24/05/2019)
Study Registration	Intended: https://clinicaltrials.gov/
Study Category and Rationale	Not applicable
Background and Rationale	In a DRG system, insufficient or incorrect coding negatively impacts reimbursement. Assuming the DRG system in use to be optimal, the quality and efficacy of treatment could be improved if reporting and demission are electronically controlled and adjusted to the DRG system in use. In the long term, a fair reimbursement might reduce the pressure on the staffing ratio and thus increase the patient safety.
Risk / Benefit Assessment	The participants are not exposed to any intervention. A more accurate reporting and a treatment more adherent to the pre-setting of the DRG system in use by specially trained physicians should not impose any risk to the participants.
Objective(s) and Endpoint(s)	Primary endpoint: • Total reimbursement per day of hospital stay Secondary endpoints: • Length of hospital stay • Total reimbursement per case • Case mix index • Severity of perioperative complications • Readmission rate (safety endpoint)
Study Design	monocentric, randomized two-arm un-blinded study
Statistical Considerations	Continuous data are analysed using non-parametric Mann-Whitney U-tests because of skewed distributions of the data. Categorical data will be analysed using Chi-square-statistics.
Inclusion- / Exclusion Criteria	All inpatients hospitalized at the department of surgery undergoing any surgical procedure not eligible for ambulant operation at the Kantonsspital St. Gallen are included. No exclusion of vulnerable patients is planned.
Number of Participants with Rationale	According to a simulation study, a total of 1200 patients and 600 patients per arm are needed to detect an increase of 5% in the reimbursement per day of hospital stay with a power of 90%.
Study Intervention	In the intervention arm, reporting and the time of demission are crosschecked and corrected by physicians with special awareness of the DRG system during the hospital stay (preliminary precoding).
Control Intervention	In the control arm the coding for DRG grouping is performed after the patient's demission. Reports are not screened for conformability to the DRG coding system.
Study procedures	In the intervention arm, reporting and the time of demission are crosschecked and corrected by physicians with special awareness of the DRG system during the hospital stay (preliminary precoding).
Study Duration and Schedule	Planned 06/2019 of First-Participant-In Planned 01/2020 of Last-Participant-Out
Investigator	Dr. Thomas Steffen, Department of Surgery, Kantonsspital St. Gallen, St. Gallen, Switzerland E-mail: Thomas.Steffen@kssg.ch Phone: +41714941314

Study Centre(s)	Kantonsspital St. Gallen, St. Gallen, Switzerland
Data privacy	No additional data exceeding the routine clinical data are generated. The electronic processing of these routine clinical data will be performed in the clinical database of the surgical department which is password-protected. As an additional measure of data privacy, only physicians involved in the study will granted access to the results of electronic data processing.
Ethical consideration	The intervention assessed in this study consists of measures of quality control based on the DRG grouping. All data used for this study are already available to every physician involved in the treatment. For patients who are in the treatment group, treatment and reports are more extensively controlled by physicians. Thus the risk to overlook faults in documentation or treatment is likely to be reduced. If a more close implementation of the DRG Grouping transfers into less severe morbidity, a potential benefit for the participant would result.
GCP Statement	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP, the HRA as well as other locally relevant legal and regulatory requirements.

2 BACKGROUND AND RATIONALE

Increasing cost pressure on health care providers in combination with further developments in reimbursement systems over the past decades led to reductions of staffing ratio with possible negative consequences on patients' safety in hospital environments. Diagnosis-related group (DRG) as a system to classify hospital cases was intended to identify "the products" that a hospital provides. DRG systems are widely spread in the world and used for reimbursement since the early 1970s. In the United States of America, the system was developed to use it explicitly for reimbursement in 1982. Roughly, DRGs are assigned by a "grouper" program based on the International Classification of Diseases (ICD) diagnoses and procedures, age, sex, discharge status, and the presence of complications or comorbidities. In a DRG system insufficient or incorrect ICD coding directly leads to a negative impact on reimbursement which may increase the pressure on staffing ratio again. This leads to a negative spiral with potentially impaired patient safety. Complications and comorbidities are at risk of both, underrecognition and incomplete coding. Furthermore, in surgery chronic diagnoses are often coded insufficiently. This may be a barrier of proper diagnosis and consequently optimal treatment strategies for the individual patient. Another barrier may include the perception that some specific diagnoses are not essential to make or code because "nothing can be done" or because it is not considered relevant for the actual medical problem [1]. The ICD is a defined list of diagnoses that are used for standardized diagnoses coding. The CHOP Code Catalogue is the official Swiss catalogue of medical treatments. Both coding systems are the basis for DRG coding in Switzerland and accordingly in many other countries with different catalogues of medical treatment. Besides the actual DRG code, it seems that further factors like quality of documentation and medical coding influence the financial proceeds of a hospital case [2–7].

Therefore the main aim of present project is to determine if daily monitoring and optimization of DRG coding of individual cases lead to better reimbursement.

3 STUDY OBJECTIVES AND DESIGN

3.1 Hypothesis and primary objective

The hypothesis of present study is that the daily monitoring and optimization of DRG coding is associated with higher reimbursement. Therefore, the primary objective is to determine if the daily monitoring and optimization of DRG coding of individual cases leads to better proceeds per day.

Secondary objectives:

Comparing the following parameters with and without daily monitoring and optimization of DRG coding:

1. Length of hospital stay including entry and demission date
2. Total reimbursement per case
3. Case mix index
4. Severity of perioperative complications
5. Readmission rate

3.2 Primary and secondary endpoints

Primary endpoint

The primary endpoint is defined as the total reimbursement divided by the length of hospital stay including the entry and the demission day. Reimbursement per day was defined as the primary endpoint because it better reflects the ratio of costs and reimbursement in contrast to simple total reimbursement. When analysing the reimbursement in 2018, the distribution of total reimbursement per patient was extremely skewed. Hence, to achieve a reasonable power for statistical significance a high number of study participants would be needed.

The total reimbursement according to the DRG coding of each included patient will be provided by the financial department. At the end of the study the financial department will provide the total reimbursement for all included patients. The length of hospital stay of each patient will be extracted from the clinical database of the surgical department which is updated and monitored on a daily base. In cases of readmission within 18 days because of a related diagnosis the cases are aggregated.

Secondary endpoints

1. Length of hospital stay: The number of days of the hospital stay including the entry and the demission day will be extracted from the clinical database of the surgical department
2. Total reimbursement per case: At the end of the study a list of included patients will be sent to the financial department. Based on this list, the financial department will provide the total reimbursement per case measured in Swiss Francs.
3. Case mix index: At the end of the study a list of included patients will be sent to the financial department. Based on this list, the financial department will provide the effective cost weight of each patient.
4. Severity of perioperative complications: The severity of perioperative complications are already routinely recorded applying the Clavien-Dindo-Classification. This standardized classification is chosen to ascertain external and internal comparability. Perioperative complications of all operated patients are routinely recorded by a dedicated physician and stored in the clinical database of the surgical department.
5. Readmission rate: On a daily basis, all admissions and readmissions are routinely presented and discussed during the morning meeting of the surgical clinic. The list of readmissions will be cross checked with the randomisation list and the demission of the included patients.

3.3 Study design

This is a monocentric, randomised two-arm un-blinded study.

3.4. Study intervention

First, based on the randomisation list, for all patients randomized into the group with daily monitoring and optimization of DRG coding (treatment group), dedicated physicians control if all relevant diagnoses and procedures are correctly coded in the operation management software. If necessary, additional codable diagnoses and procedures are discussed with the operating surgeon and if appropriate the coding is changed accordingly. Finally, the internal coherence of the coding and the wording of the operation report are crosschecked. Therefore, the electronic signature procedure of operation reports will be adopted such that the report will not be sent before one of the dedicated physicians approved its final version.
Second, the dedicated physicians control if relevant diagnoses and procedures are correctly recorded in the drafts of the discharge reports. Therefore, patients in the treatment group are visited daily. In addition, the patient records are inspected and their relevance for the DRG coding is assessed. If necessary, relevant diagnoses are incorporated in the draft of the discharge report. Additionally, the matching between diagnoses and procedures listed in the discharge report is crosschecked. The optimal time of discharge of each patient is evaluated on a daily base.

To support the process described above, for all patients randomized into the group with daily monitoring and optimization of DRG coding (treatment group), a pdf file with the current DRG grouping according to the procedures and diagnoses routinely coded in the Operation management software is created. Based on these procedures and diagnoses, the current DRG grouping status is estimated. Based on the estimated DRG grouping status, the actual length of stay is compared with the lower and upper limit and the mean length of stay determined by the associated actual DRG group. Additionally, based on routinely and systemically collected data in the clinical database of the surgical department, potential secondary diagnoses relevant for reimbursement are generated by computerized algorithms. For each potential secondary diagnosis, the hypothetical DRG Grouping considering the already coded procedures and diagnoses is estimated. The possible secondary diagnoses are deducted from laboratory measurements, from the extended Charlson comorbidity score routinely evaluated preoperatively by the department of anaesthesiology, and from the recording of perioperative complications.
Third, final discharge reports of patients randomized into the group with daily monitoring and optimization of DRG coding (treatment group), are controlled to ascertain the completeness of diagnoses and procedures and their concordance. Therefore, the electronic signature procedure of discharge reports will be adopted such that the report will not be sent before one of the dedicated physicians approved its final version.

In patients randomized into the control group none of the above described intervention steps will be performed. In these patients, the actual clinical routine will apply.

4 STUDY POPULATION AND STUDY PROCEDURES

4.1 Inclusion and exclusion criteria, justification of study population

All patients undergoing any elective or emergency surgical procedure not eligible for ambulant operation at the Kantonsspital St. Gallen, Department of Surgery are eligible for study. All patients screened for the trial are documented in the screening log. Patients meeting the inclusion criteria are enrolled in the trial.

Inclusion criteria

- Inpatients undergoing any surgical procedure not eligible for ambulant operation

- Operation performed at the Kantonsspital St. Gallen
- Patients hospitalised at the department of surgery at the Kantonsspital St. Gallen beginning from the starting day of the trial

Exclusion criteria

- Outpatients
- Patients who undergo operations at the hospital of Flawil or Rorschach but not at the Kantonsspital St. Gallen
- Patients operated by the department of surgery but hospitalized at any other department of the Kantonsspital St. Gallen

4.2 Recruitment, screening and informed consent procedure

For quality control reasons, data from all operations performed by the department of surgery at the Kantonsspital St. Gallen are imported regularly from the operation management system (eOPPs) into the clinical database of the surgical department on a daily base. The database is already used to analyse morbidity and mortality on a daily base.

In this database, every added operation of all patients hospitalized after the starting date of the study will be screened electronically by a sql script if the inclusion- and exclusion criteria apply on a daily base. The result of the screening is documented in a sql table and depicted in the database by a special form, where the screening results are shown as read-only data.

Informed consent is not necessary because this study exclusively aims to optimize already quality control. No intervention interfering with the medical treatment is performed.

4.3 Study procedures

The overall study duration is expected to be 7 months. The recruitment period is expected to be 6 months. Patients still hospitalized one month after the end of the recruitment period will be secondarily excluded.

4.4 Withdrawal and discontinuation

Patients still hospitalized one month after the end of the recruitment period will be excluded. Patients who are initially hospitalized at the surgical department of the Kantonsspital St. Gallen and thereafter transferred to another department will be excluded from the analysis.

5 STATISTICS AND METHODOLOGY

5.1. Statistical analysis plan and sample size calculation

Statistical analyses will be performed by Dr. med. Rene Warschkow, MSci in biostatistics (Heidelberg University/Germany). Dr. Warschkow performed the sample size calculation. Sample size calculation and statistical analyses will be performed using the R statistical software.

Sample size calculation

Sample size calculation was performed in a separate simulation study using the total reimbursement divided by the length of hospital stay for the surgical department of the Kantonsspital St. Gallen in 2018. Sample size estimation was based on a two-sided significance level of $\alpha = 0.05$ and a power of 90%. The increase in reimbursement was assumed to be 5% in the intervention group. Furthermore, in 15% of patients a shortening of the length of stay by one day was assumed in the intervention group. Randomization was 1:1. A drop-out rate of 10% was assumed. Based on this assumptions, a total of 1200 patients (600 per group) would be needed

to prove a significant increase in the total reimbursement divided by the length of hospital stay. According to the case load in 2018, the recruitment period would last 6 months.

Statistical analysis plan

The primary endpoint total reimbursement divided by the length of hospital stay will be analysed by a nonparametric Mann-Whitney U-test. For the secondary endpoints Length of hospital stay, total reimbursement per case, and Case mix index the Mann-Whitney U-test will be applied too. For the secondary endpoint severity of complications both a Mann-Whitney U-test and a Chi-Square test will be applied. For the secondary endpoint rehospitalisation rate, a Chi-Square test will be applied. Auxiliary multivariable analyses for continuous outcomes will be performed using the mean ranks.

No interim analysis and no multiple testing is planned.

5.2. Handling of missing data and drop-outs

In case of missing data and drop-outs a complete case analysis is performed.

5.3. Randomization

Randomization will be performed using the R sample function. 1:1 Randomisation will be performed in random block sizes of 4, 6 and 8. Randomisation will be performed automatically by the same sql script which is used for screening.

6 REGULATORY ASPECTS AND SAFETY

6.1 Local regulations / Declaration of Helsinki

This study is conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP If the clinical trial is not conducted according to ICH-GCP guidelines, the paragraph above must be adapted accordingly (ClinO Art. 5, Abs 2), the HRA as well as other locally relevant legal and regulatory requirements.

6.2 (Serious) Adverse Events

Due to the character of the invention, causal relationships between any Serious Adverse Event (SAE) or Adverse Event (AE) and the intervention can generally be ruled out.

Reporting of SAEs (see ClinO, Art. 63)

All SAEs are documented and reported immediately (within a maximum of 24 hours) to the Sponsor-Investigator of the study.

If it cannot be excluded that the SAE occurring in Switzerland is attributable to the intervention under investigation, the Investigator reports it to the Ethics Committee via BASEC within 15 days.

Follow up of (Serious) Adverse Events

Describe the follow up procedures of participants terminating the study with reported ongoing (S)AEs until resolution or stabilisation.

6.3 (Periodic) safety reporting

One safety report is submitted once 3 Months after the starting date of the study to the local Ethics Committee by the Investigator (ClinO, Art. 43 Abs).

6.4 Radiation

No radiation is performed in this study.

6.5 Pregnancy

No reporting of pregnancies is planned.

6.6 Amendments

Substantial changes to the study setup and study organization, the protocol and relevant study documents are submitted to the Ethics Committee for approval before implementation. Substantial amendments are changes that affect the changes in the protocol that affect study objective(s) or central research topic, changes of study site(s) or of study leader and sponsor (ClinO, Art. 29).

6.7 (Premature) termination of study

Upon regular study termination, the Ethics Committee is notified via BASEC within 90 days (ClinO, Art. 38).

Upon premature study termination or study interruption, the Ethics Committee is notified via BASEC within 15 days (ClinO, Art. 38).

6.8 Insurance

As no study-related damage or injuries can occur, no insurance is necessary.

7 FURTHER ASPECTS

7.1 Overall ethical considerations

The intervention assessed in this study consists of measures of quality control based on the DRG grouping. All data used for this study are already available to every physician involved in the treatment.

7.2 Risk-benefit assessment

For patients who are in the treatment group, treatment and reports are more extensively controlled by physicians. Thus the risk to overlook a fault in documentation or treatment is likely to be reduced. If a more close implementation of the DRG Grouping transfers into less severe morbidity, a potential benefit for each participant can be assumed.

8 QUALITY CONTROL AND DATA PROTECTION

8.1 Quality measures

For quality assurance the sponsor or the Ethics Committee may visit the research site. Direct access to the source data and all study related files is granted on such occasions. All involved parties keep the participant data strictly confidential.

8.2 Data recording and source data

The result of the screening and randomisation is documented in a read-only sql table in an already implemented clinical database of the department of surgery. In this password-protected database,

an audit trail is implemented. Data concerning primary and secondary outcomes are provided by the financial department upon request at the end of the study. No

8.3 Confidentiality and coding

Trial and participant data will be handled with uttermost discretion and is only accessible to authorised personnel who require the data to fulfil their duties within the scope of the study. Participant identification data are protected from unauthorised or accidental disclosure, alteration, deletion, copying and theft by password protection, limited access to the database, hourly backup, and by hosting the database on an exclusive server without internet connection.

8.4 Retention and destruction of study data and biological material

All study data are electronically archived for 10 after study termination or premature termination of the study.

9 MONITORIMG AND REGISTRATION

No regular monitoring visits at the investigator's site are planned. Source data/documents are accessible to the sponsor or the Ethics Committee. Registration in a national language in the Swiss National Clinical trial Portal (SNCTP via BASEC) will be performed. In addition, the study will be registered at clinicaltrials.gov.

10. FUNDING / PUBLICATION / DECLARATION OF INTEREST

No funding is planned. The findings will be published to an adequate peer reviewed journal with the following authorship:

Steffen T, Warschkow R, Widmann B, Roeske S, Bock S, Tarantino I

11. REFERENCES

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