Protocol:

Written detailed procedure for conducting the research study and collecting data.

Protocol

- The contents of a trial protocol should generally include the following topics. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as Investigator's Brochure.

GBOT SET SI REFAQ

1- General information:

1. Protocol title, protocol identifying number, and date.

Any amendment(s) should also bear the amendment number(s) and date(s).

2. Name and address of the sponsor and monitor (if other than the sponsor).

3. Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.

4. Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.

5. Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

6. Name, title, address and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).

7. Name(s) and address(es) of the clinical laboratory (ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

2. Background information:

i - Name and description of the investigational product(s)

ii. A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.

iii. Summary of the known and potential risks and benefits, if any, to human subjects.

iv. Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).

V. A Statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).

Vi. Description of the population to be Studied.

Vii. References to literature and data that are relevant to the trial, and that provide background for the trial.

3. Trial objectives and purpose:

A detailed description of the objectives and the purpose of the trial.

4. Trial design:

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design.

A description of the trial design, should include:

i. A specific statement of the primary endpoints and secondary endpoints, if any, to be measured during the trial.

ii. A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.

iii. A description of the measures taken to minimize/avoid bias, including a. randomization

b. Blinding

iv. A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labelling of the investigational product(s).

v. The expected duration of subject participation, and a description of the sequence and duration

of all trial periods, including follow-up, if any.

vi. A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial.

vii. Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.

viii. Maintenance of trial treatment randomization codes and procedures for breaking codes.

ix. The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.

5. Selection and withdrawal of subjects:

i. Subject inclusion criteria

ii. Subject exclusion criteria

iii- Subject withdrawal criteria (i.e terminating investigational product treatment /trial treatment) and procedures specifying:

a) When and how to withdraw subjects from the trial/ investigational product treatment.

b) The type and timing of the data to be collected for withdrawn subjects

c) Whether and how subjects are to be replaced

d) The follow-up for subjects withdrawn from investigational product treatment/ trial treatment.

6. Treatment of Subjects:

i- The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects

for each investigational product treatment /trial treatment group/arm of the trial.

ii- Medication(s)/ treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.

iii- Procedures for monitoring subject compliance.

7. Assessment of efficacy:

i- Specification of the efficacy parameters.

ii. Methods and timing for assessing, recording and analysing of efficacy parameters.

8. Assessment of safety:

i- Specification of safety parameters

ii- The methods and timing for assessing, recording and analysing safety parameters.

iii- Procedures for eliciting reports of and for

recording and reporting adverse event and intercurrent illnesses.

iv. The type and duration of the follow-up of subjects after adverse events.

9. Statistics:

i. A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).

ii- The number of subjects planned to be enrolled In multicentre trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on(or calculations of) the lower of the trial and clinical justification.

iii. The level of significance to be used.

iv- Criteria for the termination of the trial.

v. Procedure for accounting for missing, unused, and spurious data.

vi. Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).

7. The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).

10. Direct Access to Source Data/documents:

The Sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC reviews and regulatory inspection(s), providing direct

access to source data/documents.

11. Quality Control and Quality Assurance:

12. Ethics:

Description of ethical considerations relating to the trial.

13. Data handling and record keeping

14. Financing and insurance

Financing and insurance if not addressed in a separate agreement.

15. Publication policy:

Publication policy, if not addressed in a separate agreement.

16. Supplements

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES,
BANGALORE, KARNATAKA

ANNEXURE- II

PROFORMA OF REGISTRATION OF SUBJECT FOR DISSERTATION

1)	NAME OF THE CANDIDATE AND ADDRESS	HEDIEH FAROKHI KOUROSH ALLAHDINI HESAROEYEH REZA RAHIMI(PB)
2)	NAME OF THE INSTITUTION	VISVESWARAPURA INSTITUTE OF PHARMACEUTICAL SCIENCES, BANASHANKARI-II STAGE, BANGALORE-70
3)	COURSE OF THE STUDY AND SUBJECT	PHARM D
4)	DATE OF ADMISSION TO THE COURSE	NOVEMBER-2011 SEPTEMBER-2014(PB)
5)	TITLE OF THE TOPIC	ASSESSMENT OF RISK FACTORS AND DRUG THERAPY FOR SURGICAL SITE INFECTIONS

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6.0	BRIEF RESUME OF THE INTENDED WORK

6.1) Need for the study

Surgical site infection is a type of healthcare-associated infection in which a wound infection occurs after an invasive (surgical) procedure. Surgical site infections have been shown to compose up to 20% of all of healthcare-associated infections. At least 5% of patients undergoing a surgical procedure develop a surgical site infection. Most surgical site infections are caused by contamination of an incision with microorganisms from the patient's own body during surgery.

Surgical site infections can have a significant effect on quality of life for the patient. They are associated with considerable morbidity and extended hospital stay. In addition, surgical site infections result in a considerable financial burden to healthcare providers. Advances in surgery and anaesthesia have resulted in patients who are at greater risk of surgical site infections being considered for surgery.[1]

CLASSIFICATION:

There are 3 different types of surgical site infection defined by the Centers for Disease Control and Prevention (CDC). In the criteria put forth by the CDC, SSIs are classified as either incisional or organ/space, with incisional SSIs being further sub classified as superficial (involving only skin and subcutaneous tissue) versus deep (involving underlying soft tissue) Centers for Disease

1)Superficial Incisional SSI

Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision.

2)Deep Incisional SSI

Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissues (eg. fascial and muscle layers).

3)Organ/Space SSI

Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (eg. organs or spaces), other than the incision, which was opened or manipulated during an operation[2].

SYMPTOMS:

An SSI may cause:

- Fever more than 100.5°F 48 hours or more after surgery
- Chills
- Fast heart rate
- Chest pain

- Symptoms in the area where the surgery took place:
  - Redness
  - Drainage
  - Pus
  - Pain
  - Swelling
  - Bad odour [3]

RISK FACTORS:

The risk of SSI is increased by factors that:

- increase the risk of endogenous contamination (for example, procedures that involve parts of the body with a high concentration of normal flora such as the bowel)
- increase the risk of exogenous contamination (for example, prolonged operations that increase the length of time that tissues are exposed)
- diminish the efficacy of the general immune response (for example, diabetes, malnutrition, or immunosuppressive therapy with radiotherapy, chemotherapy or steroids) or local immune response (for example, foreign bodies, damaged tissue or formation of a haematoma).[4]

The degree of risk for an SSI is linked to the type of surgical wound you have. Surgical wounds can be classified in this way:

- Clean wounds. These are not inflamed or contaminated and do not involve operating on an internal organ; the risk for an SSI in this type of wound is less than 2 percent.
- Clean-contaminated wounds. These have no evidence of infection at the time of surgery, but do involve operating on an internal organ; the risk for SSI is less than 10 percent.
- Contaminated wounds. These involve operating on an internal organ with a spilling of contents from the organ into the wound; the risk for SSI is 13 to 20 percent.
- Dirty wounds. These are wounds in which a known infection is present at the time of the surgery; the risk for SSI is about 40 percent.[5]

TREATMENT:

Medicines:

The following medicines are commonly administered:

- Antibiotics: This medicine is given to help treat or prevent an infection caused by bacteria. Antibiotics are warranted when local cellulitis or wound necrosis is present[6]

- Medicines to treat pain, swelling, or fever: These medicines are safe for most people to use. However, they can cause serious problems when used by people with certain medical conditions. Treatment options:
- Cleansing: Cleansing may be done by rinsing the wound with sterile (clean) water.
- Debridement: This is done to clean and remove objects, dirt, or dead skin and tissues from the wound area. Caregivers may cut out the damaged areas in or around the wound.
- Hyperbaric oxygen therapy: This is also called HBO. HBO is used to get more oxygen into your body. The oxygen is given under pressure to help it get into your tissues and blood.
- Negative pressure therapy: This is also called vacuum-assisted closure (VAC). A special foam dressing with an attached tube is placed inside the wound cavity and tightly covered.
- Wound dressings: Dressings (bandages) are used to protect the wound from further injury and infection. They may also help provide pressure to decrease swelling. [7]

6.2) REVIEW OF LITERATURE:

- A study was conducted by Cheng K et al to determine risk factors for surgical site infection in a teaching hospital which included 1138 patients. The study included patients who underwent breast, hernia, esophagus, stomach, appendix, colon or rectal surgery in range of 2-92 years old. Risk factors assessed were type of operation, wound classification, volume of blood loss, blood transfusion, risk index, duration of surgery, diabetes, cancer, gastrointestinal catheter, urinary catheter, post operative drainage and pre-procedural WBC count could be regarded as potential indicators of SSI and that relevant preventive measures should be taken to reduce SSI and improve patient outcome [8]
- A study was conducted by Justin E Richards et al to determine Stress-Induced Hyperglycemia as a risk factor for surgical-site infection in non-diabetic Orthopaedic trauma patients admitted to the intensive Care Unit. This study included one hundred and eighty-seven consecutive trauma patients with isolated orthopaedic injuries. Blood glucose values during initial hospitalization were recorded. The admission blood glucose (BG) and hyperglycemic Index (HGI) were determined for each patient. Perioperative infectious complications found were pneumonia, urinary tract infection (UTI), surgical-site infection (SSI), sepsis. Stress-induced hyperglycemia demonstrated a significant independent association with SSI's in non-diabetic orthopedics trauma patients who were admitted to the ICU.[9]
- A study was carried out by Margaret A Olsen et.al to determine risk factors for surgical site infection following major breast surgery. A retrospective case control study design was used to determine independent risk factors for surgical site infection in subjects selected from a cohort of patients who had undergone mastectomy, breast reconstruction or reduction surgery

between January 1998 and June 2002 at a tertiary care university affiliated hospital. The medical records of 57 patients with breast SSI and 268 randomly selected uninfected were taken as case selected for control were reviewed. Suboptimal prophylactic antibiotic dosing is a potentially modifiable risk factor for SSI following breast surgery. Risk of SSI was increased in patients undergoing mastectomy and in patients who had an implant or tissue expander placed during surgery. Knowledge of these risk factors can be used to develop a specific risk stratification index to predict SSI in breast surgery and infection preventive strategies tailored for breast surgery patients[10].

- A study was conducted by Albert F Pullter Gunne et al to determine incidence of surgical site infection following adult spinal deformity surgery. This study was retrospectively performed on a large case cohort of all adult patients who underwent surgery for kyphosis or scoliosis. Preoperative patient characteristics including age, gender, weight, Presence of obesity , co morbidities, use of non steroidal anti inflammatory drugs, serum albumin level, serum protein level and serum white blood cells count were recorded. In this retrospective cohort analysis, 830 adult patients underwent surgery for a spinal deformity (kyphosis/scoliosis), 46 patients (5.5%) developed a SSI, out of which 17 patients (2.0%) had an isolated superficial SSI, and 29 patients (3.5%) had a deep SSI. Obese patients were found to have an increased risk for all types of SSI, while patients who had a prior SSI were at increased risk for recurrent SSI. An anterior/posterior procedure on the same day has a tendency to increase the risk for SSI. By understanding these findings, protocols can be developed to decrease the rate of SSI in this high risk population[11].
- A study was conducted by Tingting Ren et al to determine risk factors for surgical site infection of pilon fractures. The medical records of all pilon fracture patients who underwent surgical fixation from January 2010 to October 2012 were reviewed to identify those who developed a surgical site infection. A total of 519 patients were enrolled in the study from January 2010 toOctober 2012. This study included patients aged above 18 years who underwent surgical fixation of a pilon fracture during the study period; and at least 12 months of clinical and radiographic follow-up. Patients exhibiting the risk factors identified in this study were counseled regarding the possible surgical site infection that may develop after surgical fixation.[12]
- A study was conducted by AeuMuro G.Lake et al to determine surgical site infection following cases during the hysterectomy. They conducted a cross sectional analysis of the 2005-09 American College of Surgeons National Surgical Quality Improvement Program used the data files to analyze case of hysterectomies. A total of 13,822 women were included in their final analysis. Their finding of the decreased occurrence of superficial SSI after vaginal approach for hysterectomy reaffirms the role for vaginal hysterectomy as the route of choice for hysterectomy.[13]
- A study was conducted by Jadranka Maksimovic et al to determine surgical site infections in orthopedic patients. A 6-month prospective cohort study on 227 patients, with 30 days of patient follow-up after surgery, was conducted at the teaching hospital in Belgrade. They collected patients' basic demographic data and data on underlying disease status, surgical procedures, preoperative preparation of patients, and antibiotic prophylaxis. It was found that

there is a high incidence of surgical site infections in orthopedic patients in Serbia in comparison with developed countries and some developing countries. Points for intervention could be reduction of personnel during surgery, better treatment of wounds, decreasing ASA score and reduction of the time between surgical site shaving and the intervention.[14]

- A study was conducted by Francois Durand et al to determine whether smoking was a risk factor for organ/space surgical site infection in orthopaedic surgery with implant materials. This study included a prospective cohort of 3,908 patients from June 2003 to December 2006. Smoking was found to be a significant risk factor for organ/space SSI. A significant difference between smokers and non-smokers for surgical wound complications (hematoma, discharge or wound dehiscence) during the period between surgical procedure and discharge from hospital.[15]

- A study was conducted by Demisew Amenu et al to determine surgical site infection rate and risk factors among obstetric cases of Jimma university specialized hospital in southwest Ethiopia. It was seen that surgical site infections rates are higher than acceptable standards indicating the need for improving antenatal care, increasing the number of skilled birth attendants at the local clinics, increasing basic and comprehensive emergency obstetric care services, applying improved surgical techniques and improving infection prevention practices to decrease infection rate to acceptable standard.[16]

- A study was conducted by Keith S.Kaya et al to determine the impact of surgical site infection on older operative patient. Retrospective matched outcomes study was used in eight hospitals including Duke University Medical Center and 7 community hospitals. On the Patients ≥ 65 years old undergoing surgery from 1991-2003. Cases were defined as patients who developed deep incisional or organ/space SSI and controls were operative patients who did not develop SSI. Controls were frequency matched to cases by type and year of operative procedure and by hospital in a 1:1 ratio. In this study they measured mortality, duration of hospitalization (including re-admissions) and hospital charges for the 90 days following surgery.1,337 patients were enrolled in the study: 561 cases with SSI and 576 control patients without SSI. Among elderly operative patients, SSI was associated with an almost 4-fold increase in mortality, a mean attributable duration of hospitalization after surgery of 15.7 days (95% CI 13.9, 17.6) and mean attributable hospital charges of $43,970 (95% CI $31,881, $56,060). [17]

6.3) OBJECTIVES OF THE STUDY :

1. To identify the risk factors associated with surgical site infection (SSI)
2. To study drug therapy given during the SSI

7.0) MATERIALS AND METHODS :-

7.1) Source of Data :

1. Treatment chart/case sheet, lab report.

7.2) INCLUSION CRITERIA:

Hospitalised in-patients undergoing surgery in the department of surgery at Kims hospital and research center

7.3) EXCLUSION CRITERIA

OPD procedure and other types of healthcare infection that mainly affect surgical patients are postoperative respiratory and urinary tract infections, bacteraemias(including methicillin-resistant Staphylococcus aureus infections and intravascular cannula infection) and antibiotic-related diarrhoeas(particularly clostridium difficle enteritis).

7.4) METHOD AND COLLECTION OF DATA:

Data will be collected from in-patients who are undergoing emergency and elective surgeries.
Direct observation of wound health professional from the department of Surgery.

Identification of potential risk factors:

- Age
- Sex
- Obesity
- Chronic disease
- Days spend preoperative/Number of days
- Previous hospitalization within past 2 weeks
- Intra-operative finding of infection
- Duration of surgery/Less than 60 min or greater than 60 min
- Drain or inserted
- Antibiotics administration if yes, details of antibiotic
- Wound classification (clean/clean contaminated/contaminated/dirty)
- Days spend at hospital postoperatively
- Nature of surgery (elective or emergency)
- Preoperative shower

Drug therapy:

Drug given

First dose

- previous days
- inward >120 min before incision
- inward <60 min
- inward between 60 to 120 min
- in OT
- after incision

	Intraoperative dose(Yes/No) Last dose
	7.5) Duration of the study: The study will be conducted for a period of 6 months.
	7.6) Place of Study: Surgery department ,KIMS hospital Bangalore
	7.7) Does the study require any investigation or intervention to be conducted on patient or other humans or animals if so, please describe briefly -No-
	7.8) Has ethical clearance been obtained from your Institution? Applied for ethics committee for the approval.

8.0)	LIST OF REFERENCES

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2) Reducing Surgical Site Infections by David E Reichman published in2009

3) Surgical Site Infection(SSI; Surgical Wound Infection)by Patricia Griffin Kellicker, BSN

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9.0	NAME & SIGNATURE OF THE CANDIDATE	Hedieh Farokhi Kouroush Allahdini hesaroeyeh Reza Rahimi
10.0	REGISTRATION NUMBER	
11.0	NAME AND DESIGNATION OF THE GUIDE	Dr.Vanaja K Assistant Professor VIPS, Bangalore.
11.1	REMARKS OF THE GUIDE	
11.2	SIGNATURE OF THE GUIDE	
12.0	NAME OF THE HEAD OF THE DEPARTMENT	Dr.Githa Kishore Professor, VIPS, Bangalore.
12.1	SIGNATURE OF THE HEAD OF THE DEPARTMENT	
13.0	NAME AND DESIGNATION OF CO-GUIDE	Dr. Lakshmi.S Assistant Professor Department of Surgery KIMS Hospital and Research Centre, Bangalore
13.1	SIGNATURE OF THE CO-GUIDE	
14.0	NAME OF THE PRINCIPAL	Dr. G.Y Narmada
14.1	REMARKS OF THE PRINCIPAL	
14.2	SIGNATURE OF PRINCIPAL WITH SEAL	