Preoperative Chlorhexidine Gluconate Bathing Could Prevent Post-obstetric and gynecologic Surgical-site Infections: A Pilot for a Randomized Controlled Trial

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Main Information

Primary registry identifying number
LBCTR2019121361

Protocol number
HD2305

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
20/12/2019

Primary sponsor
Beirut Arab University

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
24/12/2019

Date of registration in national regulatory agency
20/12/2019

Public title
Preoperative Chlorhexidine Gluconate Bathing Could Prevent Post-obstetric and gynecologic Surgical-site Infections: A Pilot for a Randomized Controlled Trial

Acronym

Scientific title
Preoperative Chlorhexidine Gluconate Bathing Could Prevent Post-obstetric and gynecologic Surgical-site Infections: A Pilot for a Randomized Controlled Trial

Acronym

Brief summary of the study: English

Background: Bathing with chlorhexidine gluconate is a novel practice that reduces the microbial burden on skin. There is limited data on chlorhexidine gluconate bathing in obstetric and gynecological surgeries in Lebanon.
Objective: To test the feasibility of a randomized controlled trial through a pilot design to evaluate the effect of preoperative chlorhexidine gluconate bathing on reducing surgical-site infections in obstetric and gynecological surgeries involving abdominal incisions.
Methods: Participants will be randomized into the intervention or usual care group. Participants in the intervention group will bath with 4% chlorhexidine gluconate sponge on the day of the surgery. They will apply the product between the upper two-thirds of the thighs and abdomen just below the breasts for 5 minutes. The rest of the body will be bathed normally as usual care. The bathing will be consistent by all participants. While participants in the usual care group will be left to practice what the healthcare facility usually advises them to do. Outcomes will be collected at day 10 and 30 after the surgery for surgical site infections defined by the presence of pus in the wound in addition to possible redness, warmth, discharge or dehisces in the wound or infectious morbidity such as fever or abdominal pain.

Brief summary of the study: Arabic

هذه الدراسة تختبر تأثير استخدام كلورهيكسيدين جلوكونيت في التعقيم قبل اجراء العمليات الجراحية التوليدية والمتعلقة بأمراض النساء على خفض احتمال حدوث الالتهابات في منطقة الجرح.
سينقسم المشتركون في الدراسة عشوائياً الى مجموعتين، حيث ستستخدم مجوعة منهم الكلورهيكسيدين في تعقيم المنطقة ما بين البطن وحتى ثلثي الفخدين، والأخرى ستستخدم الأساليب التقليدية في التعقيم لدى المستشفى.
أما النتائج، فستجمع بعد 10 و 30 يوم من تاريخ إجراء العملية لوجود اي مؤشر للالتهابات .

Health conditions/problem studied: Specify

Infection post-surgery on the surgical site

Interventions: Specify

A daily visit to the named hospitals will be done by Researcher I to check the following day's operating room schedule for any planned OBS/GYN abdominal surgeries. Participants with planned surgeries will be approached upon admission and introduced to the study. Each participant will be allocated to a study code. Participants will sign the consent form and complete the baseline questionnaire. They will then be randomized based on their study code. Participants allocated to the intervention group will be instructed by Researcher I on the use of CHG before leaving to the surgery. CHG will be provided to the participants to perform the bath. Participants will be instructed to emphasize the CHG application between the upper two-thirds of the thighs and abdomen just below the breasts for 5 minutes. The rest of the body will be bathed normally as usual care. Same instructions will be given to all participants in the intervention group by the same researcher to assure consistency. Tools and figures will be used to enhance explanation. Adherence to intervention will be assured when giving the antiseptic and asking to bath immediately.

Key inclusion and exclusion criteria: Inclusion criteria

Adult women presenting to the hospitals OBS/GYN pre-surgery wards during the study period; they will be included if they were presented for a planned surgery, consenting to participate and will be available for follow up, regardless of their nationality.

Key inclusion and exclusion criteria: Gender

Female

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

45

Key inclusion and exclusion criteria: Exclusion criteria

Participants will be excluded if they have known allergy to chlorhexidine or have a condition impeding them from participation such as blindness, deafness or cognitive impairment.

Type of study

Interventional

Type of intervention

Educations programs

Type of intervention: Specify type

N/A

Trial scope

Prophylaxis

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Placebo

Study phase

0 (explanatory trials)

Study design: Purpose

Prevention

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Chlorhexidine is a broad-spectrum antiseptic effective against Gram-positive and negative bacteria (WHO, 2008).

Therapeutic indication

CHG reduces microbial colonization on the skin, and thus, is used in many of the hospitals to reduce the risk of having health-care associated infections.

Therapeutic benefit

Chlorhexidine is used for disinfection instead of Betadine in many of the hospitals, but its effect has not yet been established in reducing the risk of infection; therefore, this trial is being conducted to evaluate its effect on reducing the risk of post-operative infections in the site of the surgical wound.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

WBC will be assessed after 10 days from surgery to detect any presence of infections.

Target sample size

40

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

03/02/2020

Date of study closure: Type

Anticipated

Date of study closure: Date

29/05/2020

Recruitment status

Pending

Recruitment status: Specify

Date of completion

29/05/2020

IPD sharing statement plan

No

IPD sharing statement description

Data will be shared if the reviewers find it necessary to maintain confidentiality and avoid the risk of breathing confidential data that may be identifiable due to the small sample size and the small community.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Beirut Arab University	01300110

Sources of Monetary or Material Support

Name
Dr. Hiba Deek
Ms. Nour Shbaklo

Secondary Sponsors

Name
none

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Hiba Deek	Beirut	Lebanon	01300110	h.deek@bau.edu.lb	BAU
Scientific	Hiba Deek	Beirut	Lebanon	01300110	h.deek@bau.edu.lb	BAU

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Rafic Hariri University Hospital	Ms. Nour Shbaklo	Infection Prevention and Control	Approved
Makassed General Hospital	Ms. Nour Shbaklo	Infection Prevention and Control	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Rafic Hariri University Hospital	26/12/2018	Mrs. Abir Sinno	abir.sinno@crurhuh.com	00000000
Makassed General Hospital	18/12/2018	Ms. Loubna	research.makassed@hotmail.com	00000000

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
infection	Infection of obstetric surgical wound (O86.0)	infection

Interventions

Intervention	Description	Keyword
Use of CHG in bathing prior to surgery	Bathing with CHG from abdomen until two-thirds of the thighs	CHG

Primary Outcomes

Name	Time Points	Measure
Infection	10 and 30 days	inspection and blood tests

Key Secondary Outcomes

Name	Time Points	Measure
none	none	none

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files