



# 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 dehiscence in the wound or infectious morbidity such as fever or abdominal pain.

## Brief summary of the study: Arabic

هذه الدراسة تختبر تأثير استخدام كلور هيكسيدين جلوكونيت في التعقيم قبل إجراء العمليات الجراحية التوليدية والمتعلقة بأمراض النساء على خفض احتمال حدوث الالتهابات في منطقة الجرح. سينقسم المشاركون في الدراسة عشوائياً إلى مجموعتين، حيث ستستخدم مجموعة منهم الكلور هيكسيدين في تعقيم المنطقة ما بين البطن وحتى ثلثي الفخذين، والأخرى ستستخدم الأساليب التقليدية في التعقيم لدى المستشفى. يوم من تاريخ إجراء العملية لوجود أي مؤشر للالتهابات 30 و 10 أما النتائج، فستجمع بعد.

## 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: Control**

Placebo

**Study design: Purpose**

Prevention

**Study design: Assignment**

Parallel

**IMP has market authorization**

**Study design: Masking**

Open (masking not used)

**Study phase**

0 (explanatory trials)

**Study design: Specify purpose**

N/A

**Study design: Specify assignment**

N/A

**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