REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

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

Main Information Primary registry identifying number Protocol number LBCTR2019121361 HD2305 **MOH** registration number Study registered at the country of origin Study registered at the country of origin: Specify Yes Type of registration: Justify Type of registration Prospective N/A Date of registration in national regulatory agency 20/12/2019 **Primary sponsor** Primary sponsor: Country of origin Beirut Arab University Lebanon Date of registration in primary registry Date of registration in national regulatory agency 24/12/2019 20/12/2019 Public title Acronym Preoperative Chlorhexidine Gluconate Bathing Could Prevent Postobstetric and gynecologic Surgical-site Infections: A Pilot for a Randomized Controlled Trial Scientific title Acronym Preoperative Chlorhexidine Gluconate Bathing Could Prevent Postobstetric and gynecologic Surgical-site Infections: A Pilot for a Randomized Controlled Trial

Brief summary of the study: English

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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 كلور هيكسيدين جلوكونيت في التعقيم قبل اجراء العمليات الجراحية التوليدية والمتعلقة بأمراض النساء على خفض احتمال حدوث الالتهابات في منطقة الجرح. سينقسم المشتركون في الدراسة عشوانيا الى مجموعتين، حيث ستستخدم مجوعة منهم الكلور هيكسيدين في تعقيم المنطقة ما بين البطن وحتى ثلثي والفخدين، والأخرى ستستخدم الأساليب التقليدية في التعقيم لدى المستشفى ويوم من تاريخ إجراء العملية لوجود اي مؤشر للالتهابات30 و 10ما النتائج، فستجمع بعد

Health conditions/problem studied: Specify

Infection post-surgery on the surgical site

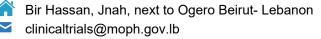
Interventions: Specify

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	Key inclusion and exclusion criteria: Specify gender
Female	
Key inclusion and exclusion criteria: Age minimum	Key inclusion and exclusion criteria: Age maximum
18	45
Key inclusion and exclusion criteria: Exclusion criteria	
Participants will be excluded if they have known allergy to chlorhe blindness, deafness or cognitive impairment.	xidine or have a condition impeding them from participation such as
Type of study	
Interventional	
Type of intervention	Type of intervention: Specify type
Educations programs	N/A
Trial scope	Trial scope: Specify scope
Prophylaxis	N/A



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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).

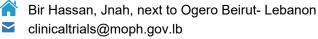
Therapeutic indication

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	Study model: Explain model
N/A	N/A
Study model: Specify model	
N/A	
Time perspective	Time perspective: Explain time perspective
N/A	N/A
Time perspective: Specify perspective	
N/A	
Target follow-up duration	Target follow-up duration: Unit
Number of groups/cohorts	
Biospecimen retention	Biospecimen description
None retained	



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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	IPD sharing statement description
No	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

Contac	Contact for Public/Scientific Queries					
Contact typeContact full nameAddressCountryTelephoneEmailAffi				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	0000000
Makassed General Hospital	18/12/2018	Ms. Loubna	research.makassed@hotmail.com	0000000

Countries of Recruitment	
Name	
Lebanon	

Health Conditions or Problems Studied		
Condition	Code Keyword	
infection	Infection of obstetric surgical wound (O86.0)	infection

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

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 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