ISRCTN15691944 https://doi.org/10.1186/ISRCTN15691944

Aloe vera gel versus olive oil for the prevention of pressure ulcers among bedridden patients

Submission date
16/07/2023

Recruitment status
No longer recruiting

Registration date
07/08/2023

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
This study aimed to compare the effects of aloe vera gel and olive oil in preventing pressure ulcers among bedridden individuals admitted in orthopaedic wards. Pressure ulcers are a prevalent issue in hospitals, leading to increased nursing care needs. Prior research suggests that aloe vera gel and olive oil can treat pressure ulcers by reducing bacterial presence and preserving skin integrity, making them potential preventive options.

Who can participate?
Patients aged 18 years or older admitted in the Orthopedics wards of selected hospitals who are at risk of pressure ulcers.

What does the study involve?
The study included two experimental groups and one control group in June 2022 to Feb 2023. The first experimental group received aloe vera gel, the second received olive oil, and the control group received routine skin care. The effectiveness of both treatments in preventing pressure ulcers was evaluated.
The assessment of pressure-prone areas was conducted over 11 days using the EPUAP and Braden scales.

What are the possible benefits and risks of participating?
Benefits include contributing to scientific knowledge, potential access to preventive treatments, medical monitoring, and potential skin health improvement. The study's findings may also improve patient care in the future. However, there are risks, such as adverse reactions to the substances, no guaranteed benefit, time commitment, discomfort, potential privacy concerns, and ethical considerations. Before joining, participants receive detailed information about the study, its objectives, potential risks, and benefits. Participation is voluntary and individuals can withdraw at any time without repercussions.

Where is the study run from?
Desh Bhagat University (India)

When is the study starting and how long is it expected to run for?
February 2021 to February 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Rajni Thapa, rajnithapa83@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Ms Rajni Thapa

ORCID ID
https://orcid.org/0000-0002-0033-7522

Contact details
Shri Mata Vaishno Devi College of Nursing
Kakryal Katra Jammu
Landmark Smvd Narayana Super Speciality Hospita
Reasi District
Katra
India
182301
+91 (0)8825022259
rajnithapa83@gmail.com

Additional identifiers

Study information

Scientific Title
Effect of aloe vera gel versus olive oil for the prevention of pressure ulcers among bedridden patients

Study objectives
Aloe vera gel reduces the incidence of pressure ulcers. Olive oil reduces the incidence of pressure ulcers.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 23/06/2021, Ethical Committee Desh Bhagat University (Desh Bhagat University Punjab and GMC JAMMU, Jammu, 180003, India; +91 (0)9855007125; research@deshbhagatuniversity.in), ref: DBU/RC/872

2. Approved 04/06/2022, EC-GMC Jammu (Govt.Medical College & Hospital, Jammu, 180003, India; +91 (0)191-2584290, 91, 92 (Exchange); +91 (0)191-2582355, 56/ 2585444 (Control Room). +91 (0)191-2584234 ; pmc-gmcjammu@jk.gov.in), ref: GMC/2022/PhD/952

Primary study design
Interventional

Study design
Interventional non-randomized clinical trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of pressure ulcers among bed ridden patients admitted in orthopaedic ward

Interventions
A quasi-experimental study including two experimental and one control group aimed at preventing pressure ulcers. Aloe vera gel was applied to experimental group 1st and olive oil was applied topically to experimental group 2 while the control group received routine skin care. All three groups evaluated the effect of aloe vera gel and olive oil in the prevention of pressure ulcers. The assessment of the pressure-prone areas was performed over the course of 11 days using the Modified EPUAP (European Pressure Ulcer Advisory Panel) scale and the Braden Pressure Ulcer Risk Assessment scale.

Intervention Type
Other

Primary outcome(s)
1. Braden pressure ulcer risk reduction score as measured by the Braden Pressure ulcer risk assessment scale at 1st day pre-assessment and 1st day post-assessment
2. Incidence of pressure ulcers measured using the modified European Pressure Ulcer Advisory Panel (EPUAP) assessment scale assessed on the 11th day

Key secondary outcome(s)
Grade/type and location/site of pressure ulcer measured using the modified European Pressure Ulcer Advisory Panel (EPUAP) assessment scale assessed on the 11th day

Completion date
10/02/2023

Eligibility

Key inclusion criteria
1. Subjects admitted in the Orthopedics wards of selected hospitals.
2. Subjects within the 48 hours of hospitalization in the orthopaedics wards with no pressure ulcers.
3. Having moderate to high risk (9-14) Braden pressure ulcer score (NPUAP).
4. Subjects willing to participate.

5. Subjects insensitivity to topical Aloe Vera gel and Olive oil.
6. Subjects aged over 18 years.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
210

Key exclusion criteria
1. Subjects who were discharge in between the data collection phase.
2. Having Mild Braden Pressure ulcer risks.
3. Reluctance to continue cooperation

Date of first enrolment
20/06/2022

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
India

Study participating centre
Government Medical College and Hospital
Maheshpura Chowk
Bakshi Nagar
Jammu
India
180003

Sponsor information

Organisation
Desh Bhagat University

ROR
https://ror.org/007n0ss86

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request Rajni Thapa, rajnithapa83@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			08/03/2024	No	No
Protocol file			21/07/2023	No	No