Usability of STAR particles in healthy volunteers: A pilot study

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PROTOCOL TITLE: Usability of STAR particles in healthy volunteers: A pilot study

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REVISION HISTORY

Revision #	Version Date	Summary of Changes
2	03NOV2023	Visit schedule changed from 2 visits to 1 visit.
3	17JAN2024	Change in payment to $80 for in-person visit and total compensation.
4.1	10APR2024	Corrections on page 8. Figure labeled Visit 2 in error. Corrected to visit 1. Changes to application site to include face. Assessing and photographing of these sites. Change from aloe gel to gel formulation of 0.7%w/w Xanthan Gum + 2.5%w/w Hydroxypropyl methylcellulose + Cyclomethicone and Dimethicone.

Table of Contents

1. Study Summary

Project Title	Usability of STAR particles in healthy volunteers: A pilot study
Project Design	Non-randomized, controlled, non-blinded, single-arm pilot (feasibility) study, with an adaptative design at mid trial.
Primary Objective	To identify the most efficacious pressure of administration and the minimum number of rubbing cycles necessary to perforate the stratum corneum.
Secondary Objective(s)	To evaluate sensation and pain during and after STAR particle application.
Exploratory Objective(s)	To assess the dispersion and disposal of the STAR particles. To evaluate the user's feedback on product use.
Research Intervention(s)/Interactions	STAR particles STAR particles are millimeter-scale particles with micron-scale projections made of biocompatible materials that painlessly disrupt the stratum corneum. As STAR particles are rubbed on skin, their microscopic projections create micron-scale pores in the stratum corneum to increase skin permeability to topical compounds independent of physicochemical properties. After the arms of the STAR particle puncture the skin, the elastic forces of the skin push the particles out. Participants will receive the 8 interventions (different application pressures) plus the control (Site and treatment will not be randomly assigned on the arm) by the investigator.
Study Population	Adults (18 to 39 years of age)
Sample Size	20
Study Duration for individual participants	1 visit to screen for medical history, examine skin, obtain informed consent, and application of the STAR particles to the participant's forearm.
Study Specific Abbreviations/ Definitions	GV – Gentian Violet; kPa - kilopascal; microneedle (MN); TEWL – trans epidermal water loss; VAPS – visual analog pain scale
Funding Source (if any)	Aldena Therapeutics (United Kingdom)
Study Site	Emory Children's Center

2. Objectives

A. Primary

1. To identify the most efficacious pressure of administration and minimum number of rubbing cycles necessary for STAR particles to penetrate the stratum corneum.

B. Secondary

1. To evaluate the sensation and pain during and after STAR particle application.

C. Exploratory

1. To assess the dispersion and disposal of the STAR particles.
2. To evaluate the user's feedback on product use.

3. Background

The objectives of this protocol are motivated by the potential future applications of STAR particles to enhance cutaneous bioavailability of topical therapies for treatment of dermatoses.

Many medical indications are treated through the topical application of a therapeutic compound that has been formulated into a gel, cream, ointment, or lotion (e.g., eczema, psoriasis, actinic keratosis, cutaneous warts, etc.) [1,2]. This is especially true in dermatology in which the skin is often the primary site of action. Topicals (i.e., drugs applied to the skin's surface) allow patients to easily self-apply these therapies without the need for painful or difficult-to-use medical technologies (e.g., hypodermic needles) or the risks associated with systemic exposure to a drug (e.g., oral, intravenous, or intramuscular administration).

Despite the advantages associated with topical delivery, the skin significantly hinders the transport of most exogenous compounds. The skin derives this functional barrier primarily from its outermost layer, the stratum corneum. The stratum corneum is approximately 10-20 µm in thickness and is composed of denucleated, terminally differentiated skin keratinocytes which form a tightly packed lipophilic shield to the outside world [3]. To overcome the skin barrier, several techniques have been employed. Various chemical, biochemical, and physical methods have been studied to increase skin permeability [4-7]. However, chemical, and biochemical methods do not appear to be broadly useful for the delivery of large molecule therapeutics (e.g., peptides, proteins, genetic material) across the skin. While physical methods have greater promise for the delivery of macromolecules, they typically involve the use of sophisticated devices that are relatively large, expensive, and/or require training. Microneedles (MNs), in contrast, can be prepared as a low-cost patch that is simple for patients to apply for the delivery of a larger range of therapeutics [8-10]. One microneedle (MN) technique that has been investigated for enhanced topical drug delivery is called "poke-and-patch." This method most commonly employs solid, non-dissolving microneedles (MNs), which are attached to a flat or cylindrical substrate, allowing for

penetration into the skin. The MNs are then removed from the skin, thereby revealing microscopic puncture sites. Subsequently, a topical formulation can be applied to the MN-treated site, and the pharmaceutical agent can passively diffuse through the created microchannels. Although this technique has shown promise to increase transport into and across the skin, there are several drawbacks to its widespread clinical adoption. These drawbacks include: (1) training users to properly apply MNs, (2) MN device sterility between treatments, (3) MN device cost, (4) complexity of a two-step application process, and (5) the small surface area of MN patches (e.g., <10 cm2) in relation to many relevant dermatoses.

4. Study Endpoints

A. Primary

1) For each primary objective, the **primary endpoint** is the identification of the most efficacious conditions measured by the number of perforations per cm^2 using GV staining and TEWL measurement before and after application of STAR particles [(T_0 (before), T_{20} (after), T_{30}, GV)].

B. Secondary

1) Evaluate the sensation and pain during and after application of STAR particle administration using questionnaires after each application.
2) Assess general safety objectives including standard adverse event (AE) reporting from enrollment until 5 days after the last visit.

C. Exploratory

1) Perform a visual inspection of the residual STAR particles to assess potential adverse events after removal.
2) To evaluate the user's feedback using a specific questionnaire.

5. Study Intervention/Investigational Agent

This is a non-randomized, controlled, non-blinded, single-arm pilot study trial, with an adaptive design at mid-trial. After 10 participants complete the study, an interim analysis will be performed and recruitment will either continue with no change to the protocol or, changes may occur in regard to the STAR particle application area, position, pressure, or rubbing cycle in an adaptive design manner.

The trial will be performed in a climatized room and participants will have time to adapt and cool down to decrease risk of modulation TEWL reading.

The investigational agent will be STAR particles made of titanium dioxide, a widely used and safe ceramic material found in sunscreens, cosmetics, and paint. The star-shaped geometry is designed to inhibit complete insertion of the particle into skin, so STAR particles do not remain embedded in the skin. After the arms of the STAR particle puncture the skin, the elastic forces of the skin push the particles out. The STAR particles will be mixed with a gel formulation of the following composition: 0.7%w/w Xanthan Gum + 2.5%w/w Hydroxypropyl methylcellulose + Cyclomethicone and Dimethicone. STAR particles will be produced by Aldena Therapeutics under GMP conditions.

6. Procedures Involved

After signing the informed consent form, eligible healthy adult participants will be enrolled in the study. The study will require one clinic visit. The visit will serve as a screening visit in order to explain the study, review inclusion/exclusion criteria, assess the participant's skin, and perform the STAR particle application. The study visit and will last approximately two hours.

A. Study visit

1) Review study
2) Assess participant skin
3) Obtain Consent
4) Apply STAR particles

B. STAR particle application

A 1.5 gram dose of STAR particles (10% concentration in gel) will be applied to the eight application sites (forearm and hand) and 100 mg of the gel without STAR particles will be applied to the control site on one of the forearms. Two rubbing cycles (30 and 60 cycles at a minimum of 1 cycle/second) and three pressures (40, 60, and 80 kPa) will be evaluated. The parameters of each STAR particle application at each site (1-9) are labelled in Figure 1. The investigator will apply the STAR particles with two fingers (index and middle fingers of the dominant hand) and the pressure point of one finger is 1 cm2. Pressures have been established with the following amount of STAR particles applied to the skin with one finger: 40 kPa (320 grams); 60 kPa (480 grams); and 80 kPa (640 grams). With two fingers, the investigator will apply with a pressure of 40 kPa when scale reads 640 grams; 60 kPa = 960 grams; and 80 kPa = 1280 grams. This will be practiced enough before the study so the investigator will know how much pressure generated on the skin based on previous practice with associating pressure according to scale weight.

C. Participants 1-10

Enrolled healthy adults will receive eight applications (three on each forearm and two to one hand) of STAR particles and one control application on the volar side of one of the forearms for a total of nine applications to the forearms. In addition, two applications of STAR particles will be applied to one of the hands – one application to the palmar surface and one to the dorsum of the hand (Figure 1).

<u>Application of STAR particles to volar side of each forearm (Figure 1)</u>

1. Wash participant's arms and hands with disinfecting soap before any application.
2. Allowed skin to dry for at least 10 minutes.
3. Investigator to delimit the 9 areas on participant's forearms and hand with a marker.
4. Measure TEWL T_0 on all 9 sites - measure from areas 1 to 9 and then from 9 to 1, giving 2 measurements for each time point according to Figure 1.
5. Apply STARs (80KPa for 60 cycles) on the dorsum of the closed hand.

6. Apply STARs (80KPa for 60 cycles) to the palmar surface of the same hand.
7. Apply STARs (pressure and # of cycles) to the six areas on the forearms per Figure 1.
8. Extra care will be taken to wash arms and hand with warm water to remove the STAR particles and gel and allowed to dry at least 5 min before the next TEWL (T_{20}) is taken.
9. Measure TEWL T_{20} on all 9 sites - measure from areas 1 to 9 and then from 9 to 1, giving 2 measurements for each time point according to Figure 1.
10. Participant completes Tolerability Questionnaire
11. Participant completes Removal & Disposal Questionnaire and User's Feedback Questionnaire.
12. Pictures (3) will be taken to assess erythema: both forearms and the hand
13. Measure TEWL T_{30} on all 9 sites - measure from areas 1 to 9 and then from 9 to 1, giving 2 measurements for each time point according to Figure 1.
14. Apply GV staining for 10 minutes on the 2 arms resting with volar arm upward and right hand on a gauze containing GV stain.
15. Wash and wipe off the GV stain thoroughly with ethanol 70%.
16. Take 3 photos of each site to visualize the puncture after GV staining.
17. Using 2 fingers (index and middle), the participant will apply pressure to a kitchen scale in an effort to mimic application of low, medium, and high pressures.
18. The investigator records the weight (from the scale) when the pressure is constant.
19. Participant is discharged.

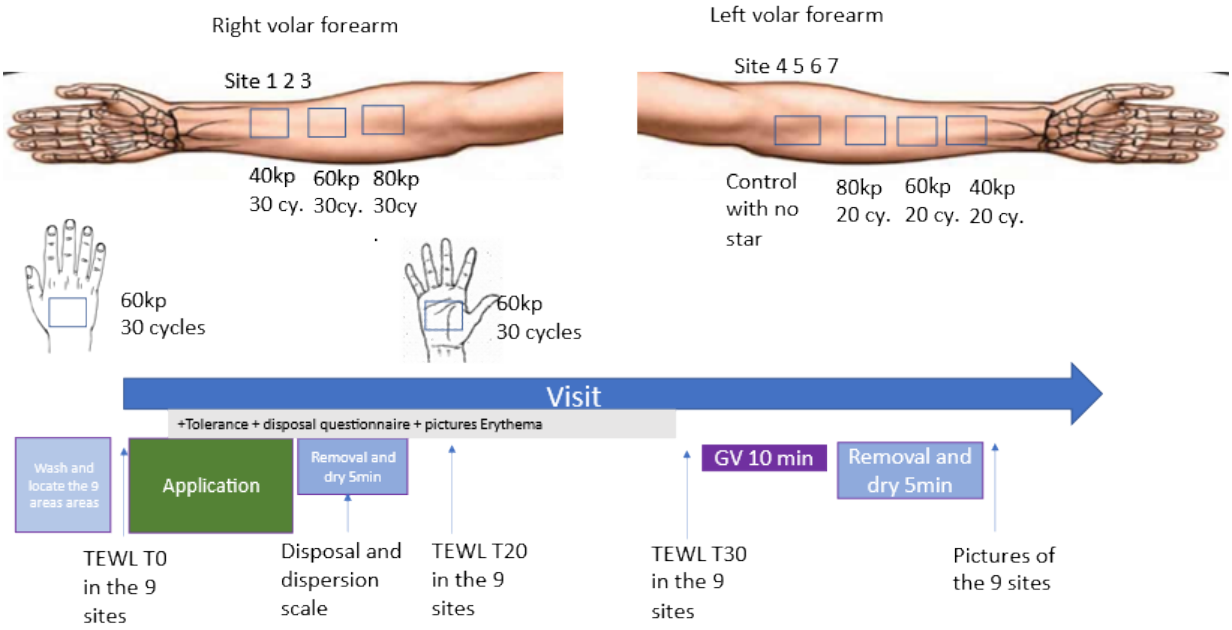

Figure 1: STAR particle application sites for V1 (participants #1-10)

D. Participants 11-20

Enrolled healthy adults will receive eight applications (one on the forearm and one on the side of the face of STAR particles and one control application on the other forearm and on the other side of the face).

Application of STAR particles to volar side of each forearm

20. Wash participant's arms and face with disinfecting soap before any application.
21. Allowed skin to dry for at least 10 minutes.
22. Investigator to delimit the 9 areas on participant's forearms and face with a marker.
23. Measure TEWL T_0 on all 4 sites - measure from areas 1 to 4 and then from 4 to 1, giving 2 measurements for each time point.
24. Apply STARs (80KPa for 60 cycles) on the forearm.
25. Apply STARs (80KPa for 60 cycles) to the side of the face.
26. Apply gel without STARs on the other forearm and on the other side of the face.
27. The study team will take photos of the application sites.
28. After approximately 5 minutes, the gel (with or without STAR particles) will be removed with a dry tissue or gauze.
29. The study team will take photos of the areas of application.
30. After the gel is removed in all areas, the investigator will examine the participant to check if there are any remaining STAR particles on the participant and/or the surrounding environment.
31. Participant completes Tolerability Questionnaire
32. Participant completes Removal & Disposal Questionnaire and User's Feedback Questionnaire.
33. Pictures (3) will be taken to assess erythema: both forearms and the face
34. Measure TEWL T_{30} on all 4 sites - measure from areas 1 to 4 and then from 4 to 1, giving 2 measurements for each time point.
35. Apply GV staining for 10 minutes on the 2 arms resting with volar arm upward and right hand on a gauze containing GV stain.
36. Wash and wipe off the GV stain thoroughly with ethanol 70%.
37. Take 3 photos of each site to visualize the puncture after GV staining.
38. Using 2 fingers (index and middle), the participant will apply pressure to a kitchen scale in an effort to mimic application of low, medium, and high pressures.
39. The investigator records the weight (from the scale) when the pressure is constant.
40. Participant is discharged.

7. Data Specimen Banking

This study will not be banking any specimens or data.

8. Sharing of Results with Participants

There are no expected incidental findings for the study. Results will not be returned to the participant.

9. Study Timelines

- Each subject will participate in the study for the 1 visit.

- The duration anticipated enrolling all study participants is 3 months.
- The estimated date for the investigators to complete this study (complete primary analyses) is 12 months.

Study Procedures and Assessments

Procedures and Assessments	Visit	1-30 days post Visit
Informed consent	X	
Medical history	X	
Inclusion and exclusion criteria	X	
Anthropometric Information	X	
Physical examination of Skin	X	
Label treating zones (9)	X	
TEWL (T_0)	X	
STAR particle application	X	
TEWL (T_{20})	X	
Complete Questionnaires	X	
VAPS & Disposal	X	
Photograph (Erythema)	X	
TEWL ($T3_0$)	X	
GV Staining	X	
Picture of GV Staining	X	
Test Pressure (on Scale)	X	
AE Reporting	X	X

10. Inclusion and Exclusion Criteria

1) Inclusion criteria:
   a. Adult, 18 – 39 years of age
   b. In good general health as determined by a medical history
   c. Willing and able to provide informed consent and follow all study requirements
   d. Not pregnant and does not desire to become pregnant in subsequent two months.
      a. Verbally confirmed with participant during consent process.

2) Exclusion criteria:

a. Has a known allergy or sensitivity to .7%w/w Xanthan Gum + 2.5%w/w Hydroxypropyl methylcellulose + Cyclomethicone and Dimethicone or alumina
b. Has any skin disorders or skin allergies
c. Has any medical condition that may affect skin or skin sensation
d. Has abnormal (e.g., tattooed) skin at forearms or face
e. Has known neurological condition affecting sensory function or perception of pain
f. Has inflammatory bowel disease
g. Has applied skin ointment or cream to forearms in the previous 24 hours
h. Has a major congenital or chromosomal abnormality known to affect skin
i. Has taken pain medication in the last 24 hours
j. Is currently participating in another interventional clinical trial
k. Has previously participated in a STAR particle interventional clinical trial
l. Has any condition (social or medical), which in the opinion of the investigator would make study participation unsafe, would interfere with adherence to the clinical study requirements, or would complicate data interpretation

11. Vulnerable Populations

The research does not contain vulnerable populations.

12. Local Number of Participants

20 healthy adults, 18-39 years of age.

13. Recruitment Methods

Participants will be recruited from students, faculty, and ancillary staff at Emory University and the Georgia Institute of Technology. Participants will be recruited through word-of-mouth and recruitment flyer. Eligibility will be reviewed through questioning the participants and examination of their skin.

14. Withdrawal of Participants

The participant may be withdrawn from the research without their consent if they are not able to follow the protocol.

Given the minimal risk associated with STAR particles and previous history of STAR particles used in humans, there does not appear to be any obvious anticipated circumstances under which participants will be withdrawn from the research without their consent.

If participants withdraw from the research, data collected will be retained and utilized as an intention-to-treat (ITT) analysis.

15. Risk to Participants

The risks to this study are minimal. We will be applying STAR particles that should puncture the skin, and due to the elastic forces of the skin, will push the particles out. From the time the STAR particles are applied to the skin, the possible risks would be expected to be local skin reactions at the site of STAR particle application including erythema, edema, tenderness, bleeding, and/or bruising.

A systemic reaction would be unlikely to occur, but due to the potential that the application and retention of STAR particles in the skin could facilitate bacterial entry into the skin, in addition to the local reactions listed above, systemic reactions including fever, cough, nausea, vomiting, diarrhea, fatigue, and headaches could also occur. Based on previous human research with STAR particles, local and systemic reactions are unlikely to occur (1). Acute skin reactions (ASRs) will be scored quantitatively with qualitative remarks as needed. The application of the STAR particles is expected to have a minimal risk to the subject. It is possible subjects could describe the placement of the STAR particles as uncomfortable or painful but based on previous human studies (1) this seems less likely. We will take precautions to prevent infections, such as using sterilized or low bioburden materials and wiping the skin with an alcohol swab before the study.

We hypothesize that the STAR particles will not remain in the skin. Our previous research on STAR particles suggests that the risk for application of STAR particles to be minimal (1).

These particles are made of titanium dioxide, a widely used and safe ceramic material found in sunscreens, cosmetics, and paint. STAR particles are designed to incorporate invisibly into topical formulations applied to skin similarly to conventional topical skin products. Based on previous clinical studies and FDA approvals of other drugs/devices using these materials, we therefore expect non-significant risk.

16. Potential Benefits to Participants

There is no direct benefit to the participant, however, there are potential future benefits to society from the understanding gained by the study.

17. Compensation to Participants

Study participants will receive a total of $100 for completion of the study. Participants will receive $80 at the completion of the in-person study visit. Participants who drive to the visit will be reimbursed for parking in the designated ECC parking area. Participants will also receive $20 30-days after the in-person study visit assuming they are able to report to the study team if they developed adverse reactions at the application sites 24-hours and 30-days after the in-person study visit.

18. Data Management and Confidentiality

Data will be stored either electronically in OneDrive or in locked offices and cabinets. The data will be stored locally until we are allowed by the sponsor or Emory to destroy them. Only staff

directly involved in completing study procedures will have access to the data. Staff listed on the delegation of authority log will be responsible for receipt and transmission of data. The coordinator or PI/Sub-I will be responsible for transporting the data locally.

If a participant declines to participate *or is ineligible to participate for any or* all portions of the study, the participant will not be assigned a study ID number and the study staff will refrain from collecting any data on the participant.

19. Provisions to Monitor the Data to Ensure the Safety of Participants

As this study is one with minimal risk, a DSMB will not be needed.

DSMP Requirement	How this Requirement is Met	Frequency	Responsible Party(ies)
Site Monitoring at pre-determined intervals: The Principal Investigator has a responsibility to ensure that the study is following all aspects of the protocol.	*There should be a standard operating procedure to review data (whether a sample or 100%) at pre-determined intervals to ensure that there is adequate documentation of critical elements such as eligibility criteria. Monitoring is required at the following timepoints (but may be done more frequently):* • *study initiation* • *at least every six months while participants are receiving intervention and* • *annually while participants are in follow-up*	*Based on risk, a review is required **annually** when participants have been enrolled.*	*Delegate a responsible party for each requirement below.* Self-assessment is acceptable.* *Self-assessment*: a process for self-assessment of protocol compliance and data integrity which can be part of an overall DSMP. See Emory's self-assessment tool on this page.
Real-time review of participant data during initial data collection.	*Will review the collected data on each participant after collecting the data.*	*Expectation is that this happens every time you obtain information.*	*Everyone on the study team responsible for primary data collection.*
100% review of consent forms	*After each participant is enrolled so that every time a participant is enrolled, his/her CONSENT FORMS will be reviewed for completeness. IN addition, forms will also be re-reviewed when all participants have completed the study.*	*After each participant is enrolled and after all participants have completed the study.*	*The Research Study Coordinator & the PI.*

Review of credentials, training records, the delegation of responsibility logs (if applicable)	*Before enrolling the first participant all credentials of all research study members will be reviewed.*	*Prior to the enrollment of the first participant.*	*The Research Study Coordinator & the PI.*
Comparison of case report forms (CRF) to source documentation for accuracy and completion	*After each enrolled participant completes the one-day study, CRFs will be compared to source documentation for accuracy and completion. In addition, these comparisons will also be made when all participants have completed the study.*	*After each participant is enrolled and after all participants have completed the study.*	*The Research Study Coordinator & the PI.*
Review of documentation of all adverse events	*For any participant who develops an adverse event during the study or after the completion of the study, we will evaluate and compare to other participants. If a similar adverse event occurs for more than 2 participants, we will review the adverse events and not continue with the study until we can ensure the study is safe. Adverse events will be assessed at the time of the study, with reports from the participants, and with follow-up contact between the study team and the participants.*	*On the day each participant is studied as well as weekly follow-up contact for one month.*	*The Research Study Coordinator & the PI.*
Monitoring of critical data points (eligibility, study endpoints, etc.)	*Prior to enrolling participants (eligibility criteria) and after each enrolled participant completes the one-day study, we will monitor the critical data points.*	*After each participant is enrolled .*	*The Research Study Coordinator & the PI.*
For FDA regulated studies, the following requirements apply:	**How this Requirement is Met**	**Timing, frequency, and intensity of monitoring**	**Responsible Party(ies)**
Monitoring methods (may include centralized, on-site, and self-assessment)	*N/A*	*N/A*	*N/A*

<u>Subject safety:</u>

- Specific subject safety parameters: subjects will report any safety-related issues or concerns to the PI (phone/email when not at a visit) or in person to the PI when at the visit.
    - Most common risk = redness to skin where STAR particles lasting less than 2 hours
    - Less Common Risks = mild irritation or small marks at the site where STAR particles applied
    - RARE risk = skin infection or foreign body growth (100 applications in > 20 participants – This has never occurred)
- Subjects will report observations:
    - During the procedure and 2 hours after the procedure is performed
    - Via follow-up contact from participant to investigating team ANYTIME after completing the study
    - Via follow-up call from investigating team 7 days after the study
- Individual responsible for safety monitoring
    - The PI will be responsible for safety monitoring.
- Subject stopping rules – under what conditions will a subject be removed from study participation and who will make the decision?
    - The study is a one-day study – if the participant has enough discomfort during the study (application of the STARS) the participant can inform the PI that he/she wants to discontinue OR, if the PI determines that the participant is in significant pain, the PI will stop the study
    - If the subject has skin irritation, pain, itching, or infection, a topical medication could be applied to address the symptoms.
    - The minimal risk associated with STAR particles makes it unlikely that a subject would develop any significant local or systemic consequence and therefore, other than subject choice or PI choice, there is not expected to be any condition that should stop the study.
- Study stopping rules - under what conditions will the study be modified or stopped and who will make the decision?
    - If 2 participants have to stop the study to discomfort, the study will be stopped and modifications will be made before resuming the study.
    - Reporting mechanisms (i.e. Deviations, adverse events, UPs)Deviations, AEs, and SAEs will be reported to the IRB by the PI according to Emory IRB reporting guidelines.
- Description of the plan for notifying the IRB of reportable events; whether the sponsor requires reporting above and beyond the Emory IRB reporting requirements, and if so, a description of the requirements and plan for meeting them.
    - We will record from participant questionnaires any adverse events and report to the sponsor (Aldena). If the adverse events are serious they will be reported to the IRB and a plan to modify the application to prevent future SAEs from occurring would be implemented.

Data Integrity:

- Specific data elements to be reviewed include pain (if any) associated with STAR particle formulation insertion, local skin findings at initial placement, and local skin findings during the study.
- Monitoring of data will occur every month after every 5 subjects are enrolled so that data will be monitored 4-5 times during the study depending on how quickly enrollment is complete.
- The PIs will be responsible for data monitoring

Additional considerations for FDA regulated trials

- All study activities except production of the STAR particles will be performed on-site
- The study team will self-monitor the study
- The study team will use Emory University's self-monitoring tool found on the CTAC website
- The first subject enrolled will trigger a self-monitoring event
- No Identification of deviations or failures that would be critical to study integrity

20. Provisions to Protect the Privacy Interest of Participants

Whenever possible, a study number, rather than the participants name will be used on study records. The participants name and other identifying information will not appear when study results are presented or published. All study documents will be kept in a locked office or secure server.

The sponsor representatives and regulatory authorities (e.g., IRB, OHRP) may inspect all documents and records required to be maintained by the investigator. The study team will permit access to such records.

Subjects will be made aware that all research activities are completely voluntary and will not impact the care they receive. They will also be informed that they are allowed to withdraw from the study at any time.

21. Economic Burden to Participants

There will be no costs for the participant associated with the research study.

22. Informed Consent

- Participants will be consented by the Principal Investigator in a private space in the ECC.
- There is no standard waiting period before the participant is approached for consent after being told about the study.

- The participant will be reminded throughout the study visit that participation is completely voluntary and that they are allowed to withdraw at any point during the visit or after the visit.
- The study will be explained thoroughly to the participant and the participant will be allowed to ask questions. The study team will give ample time to the potential participants to ask questions and decide whether they would like to participate. The participants will be reminded that the study is completely voluntary and that not participating will not affect their care for their medical condition. The staff performing the informed consent process will also ask the participant questions to verify understanding of the information relayed.

Non-English-Speaking Participants:

We will not enroll any speaking participants since we are not able to get certified translations of the study questionnaire.

23. Setting

The research will be conducted at the Emory Children's Center (ECC) on the Emory University campus. All procedures will be performed by the study investigators when subjects are present for visits. Subjects will be in contact (email/phone) with the PI to report any unexpected issues relating to STAR particle placement or skin, if it occurs when not at the ECC for a visit.

All research procedures will be performed at the Emory Children's Center on the Emory University campus.

24. Resources Available

We are performing this study as a feasibility study and believe we have enough resources to recruit the number of subjects we seek to study.

[redacted] will devote 10% time to this study.

The PI (medical physician) and the research study team will be monitoring the subjects and subjects will be able to contact the study team for any potential consequences that could come about from the research.

The PI will review the protocol and procedures with the research study team.

25. Multi-Site Research When Emory is the Lead Site

N/A

26. References

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