

213133	Spot Study																																																
Study Summary	<p>Alba Science would like to invite you to participate in a plasma home device/Skin Imperfection Study. You are being asked to participate in a research study to assess the efficacy and safety of an electrical device (ACNO Plasma shower) in combination with a cosmetic formula), compared to a topical reference product on retentional (Comedones) & inflammatory skin lesions (papula) after repeated applications. By combining the 2 treatments (device & formula), it is hoped that they will speed the effect of these treatment on imperfections.</p> <p>Approximately 70 female volunteers with oily or combination-oily spot prone skin will be recruited.</p>																																																
Attendance – 7 Visits	<p>MAIN STUDY – 7 Visits</p> <p>Appointments will run from 8:30am – 3pm – you will be given the same appointment for each visit.</p> <p>COHORT 6</p> <table border="1" data-bbox="387 801 1385 1234"> <thead> <tr> <th>Visit</th> <th>Date</th> <th>Approx. Length of Study Visit</th> </tr> </thead> <tbody> <tr> <td>Screening Visit</td> <td>Friday 09 February 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 2</td> <td>Monday 12 February 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 3</td> <td>Friday 16 February 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 4</td> <td>Friday 23 February 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 5</td> <td>Friday 02 March 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 6</td> <td>Friday 09 March 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 7</td> <td>Friday 16 March 2018</td> <td>Approx. 1 Hour</td> </tr> </tbody> </table> <p>OR</p> <p>COHORT 7</p> <table border="1" data-bbox="387 1375 1385 1805"> <thead> <tr> <th>Visit</th> <th>Date</th> <th>Approx. Length of Study Visit</th> </tr> </thead> <tbody> <tr> <td>Screening Visit</td> <td>Monday 12 February 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 2</td> <td>Thursday 15 February 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 3</td> <td>Monday 19 February 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 4</td> <td>Monday 26 February 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 5</td> <td>Monday 05 March 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 6</td> <td>Monday 12 March 2018</td> <td>Approx. 1 Hour</td> </tr> <tr> <td>Visit 7</td> <td>Monday 19 March 2018</td> <td>Approx. 1 Hour</td> </tr> </tbody> </table>	Visit	Date	Approx. Length of Study Visit	Screening Visit	Friday 09 February 2018	Approx. 1 Hour	Visit 2	Monday 12 February 2018	Approx. 1 Hour	Visit 3	Friday 16 February 2018	Approx. 1 Hour	Visit 4	Friday 23 February 2018	Approx. 1 Hour	Visit 5	Friday 02 March 2018	Approx. 1 Hour	Visit 6	Friday 09 March 2018	Approx. 1 Hour	Visit 7	Friday 16 March 2018	Approx. 1 Hour	Visit	Date	Approx. Length of Study Visit	Screening Visit	Monday 12 February 2018	Approx. 1 Hour	Visit 2	Thursday 15 February 2018	Approx. 1 Hour	Visit 3	Monday 19 February 2018	Approx. 1 Hour	Visit 4	Monday 26 February 2018	Approx. 1 Hour	Visit 5	Monday 05 March 2018	Approx. 1 Hour	Visit 6	Monday 12 March 2018	Approx. 1 Hour	Visit 7	Monday 19 March 2018	Approx. 1 Hour
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Inclusion Criteria	<p>Subjects must be:</p> <p>Healthy Female. Aged 18-40 years. Must be Fitzpatrick skin types I – IV.</p> <p>Have an oily or combination oily skin</p>																																																

Subjects with emerging skin inflammatory lesions on the face.
 Female subjects must be using an effective contraception and not have changed their contraception method in the previous 3 months or is planning to do so during the study.
 Willing not to change your usual washing products and habits (e.g. shampoo, shower gel, eyes make up removers) throughout the course of the study.
 Willingness and ability to comply with protocol requirements.
 Written informed consent form to participate in the study.

Exclusion Criteria

You will not be eligible to take part in this study if any of the following applies:

Women with irregular menstruation cycle.
 Subject free of anti-acneic or anti-seborrheic topical cosmetic products for at least 15 days before the screening visit.
 Subject free of anti-acneic or anti-seborrheic topical medical products for at least 1 month before the screening visit.
 Subject with active skin condition (psoriasis, eczema, active herpes or systemic infection).
 Subject having hairiness, moles, tattoos, scars, irritated skin etc. on the face.
 Subjects who have used tanning beds within 4 weeks or have applied self-tanning products within 1 week.
 Subjects who have changed their cosmetic washing habits for the area to be treated (Shower Gel, Shampoo) in the last 15 days before your baseline visit.
 Subject who have changed their face skin care products in the past 15 days before screening.
 Subjects who have had aesthetic care performed by a beautician (Deep Skin Cleansing) or underwent aesthetic acts performed by dermatologist (dermabrasion, peeling, light-therapy, etc) on the face in the previous 3 months.
 Subject receiving medical surgery or cosmetic surgery on the face within the last 6 months before baseline visits.

Subjects using any of the systemic or medical therapy mentioned in the table below:

Treatment name/type	Wash-out period
- Retinoids	
*topic retinoid therapy	2 months
*oral retinoid therapy	6 months
- Fibrates and statines	1 month
- Cytoproterone acetate	3 months
- Chronic therapy with corticosteroids (inhaled administration is not considered as a systemic route) or thyroid extracts	3 months
- Chronic antibiotherapy (except penicillin) : topical or oral	1 month
- Chronic NSAID (aspirin, ibuprofen, nurofen, naproxen, diclofenac) or anti-histaminic by general route	15 days

	<p>Subject who took short course treatment of corticosteroids, antibiotics or anti-inflammatory drugs (oral or topical) within the last 7 days before you baseline visit. Woman known to be pregnant, nursing or planning to become pregnant.</p>
<p>Study Restrictions</p>	<p>Volunteers will be requested to observe the following restrictions during the course of their participation in the study:</p> <ul style="list-style-type: none"> • Do not manipulate the lesions on your face (do not squeeze). • Do not change your cleansing habits (shampoo, bath/shower products, eye make-up removers). • Do not use any face skin care products (usual or new) except study products provided by Sponsor • Do not take a bath/shower/shampoo within 2 hours of your appointment time. • Do not undergo aesthetic care therapy (peeling, deep skin cleansing, light therapy, lasers, etc). • Not to use aspirin, anti-inflammatory drugs, anti-histamines or corticosteroids for the duration of the study (paracetamol is permissible for pain relief). Subjects are requested to alert test personnel of any changes to medication during this study and are informed that certain medications may fall within the exclusion criteria, and may result in their withdrawal from the study. • To refrain from having surgical or non-surgical aesthetic procedures during the study including Botox, fillers, lip enhancements, permanent or semi-permanent eyebrow or cosmetic treatments. • To refrain from exposing the facial skin to excessive natural sunlight or to other sources of UV light such as tanning beds. • Attend the test centre having refrained from applying any products to your face prior to each visit.
<p>Expenses</p>	<p>You will be paid a £130 cheque in your name on completion of this study.</p>
<p>How to Apply</p>	<p>To take part in this study please email recruitment@albavolunteers.com or call 08007561046.</p>