MINERAL MOR LTD.

Confidential

Results of the first clinical study on a new treatment for Psori asis: the T.M.S.T. method

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Conclusions: 1. No side effects were recorded during the 5-week study period. 2. A good to excellent compliance was achieved by the patients. 3. Patients were generally improved during the treatment. 4. 75% of the patients were classified as "responders" and 55% of them as exhibiting "very good results". 5. No rebound effect was recorded after stopping the treatment

Table of Contents

A first clinical trial on T.M.S.T.

Introduction

Pilot studies are used as clinical trials in order to test different doses, routes of administration, dosing schedules and possible barriers to adherence before a large-scale multicenter drug study is launched. Pilot studies are used as feasibility studies, to ensure that the ideas or methods behind a research idea are sound, as well as to "work out the kinks" in a study protocol before launching a larger study.

From Mr. Guy Lahav, the owner and marketing director of Mineral Mor Ltd. (the company which developed T.M.S.T. – see annex 1), we receive the request and the sponsorship to test this product on 14 volunteers who accepted to participate to this preliminary study.

The goals of this study were defined as follow:

1. To check eventual side effects of the product after a month of treatment
2. To determine the compliance to such a treatment involving several items and significant changes in the life style
3. To evaluate the general influence of the product on the disease
4. To grossly determine the percentage of responders (regarding the skin disease) in the population studied
5. To determine, in the responders population, whether interruption of one week induces worsening (rebound effect) or not, allowing stabilization of the disease
6. To try to define the length for optimal treatment with the tested product

Our conclusions are as follow:

1. **No side effects were recorded during the 5-week study period**
2. **A good to excellent compliance was achieved by the patients**
3. **Patients were generally improved during the treatment**
4. **75% of the patients were classified as "responders" and 55% of them as exhibiting "very good results"**
5. **No rebound effect was recorded after stopping 1 week the treatment**
6. **In our opinion, the treatment should be continued until total clearance**

Patients and Methods

Patients were enrolled through advertising and by direct call. They received an explanation about the product and the rationale of the treatment, which was proposed for free and without any compensation from the sponsor.

By accepting to participate, they agreed to take during one month the whole treatment and to come at 4 consecutive appointments, in which data about their disease will be recorded. As well, participants accepted to stop any topical treatment, except regular skin care.

Inclusion criteria were:

1. Psoriasis disease in any form, well diagnosed, in acute phase or in remission, with or without systemic or local treatment
2. Atopic dermatitis well diagnosed, in any phase

Exclusion criteria were defined as:

1. Pregnancy
2. Known allergy to one of the component of the treatment

The meetings took place during the months of November and December 2012, at the offices of T.M.S.T, in Jerusalem. We obtain from all participants a signed informed consent document (annex 2), at the first meeting, after explaining again the goals and the eventual benefits of such a study for the participants.

Side effects and unexpected events, as well as the positive influence of the product were also carefully monitored. Pictures of one lesion were taken in order to document the eventual changes. The meetings were planned once a week during 3 weeks and after 2 weeks. At each time, the patient was asked to fill a short questionnaire related to adherence to treatment, side effects and positive effects (annex 3).

Medical examination allowed to determinate a modified Psoriasis Area and Severity Index (PASI) score for patients suffering from psoriasis. The modification was in that not all lesions were evaluated but only one. The score included 3 parameters: erythema, scales and infiltration (from 0 to 4). General impression and evaluation of the investigator was also recorded (annex 4).

After 4 consecutive weeks of treatment, patients were asked to stop taking it for one week, and to come again for a last evaluation. This pause was programmed in order to check eventual "rebound effect" when stopping the treatment.

Graph 1. Schematic representation of study recruitment

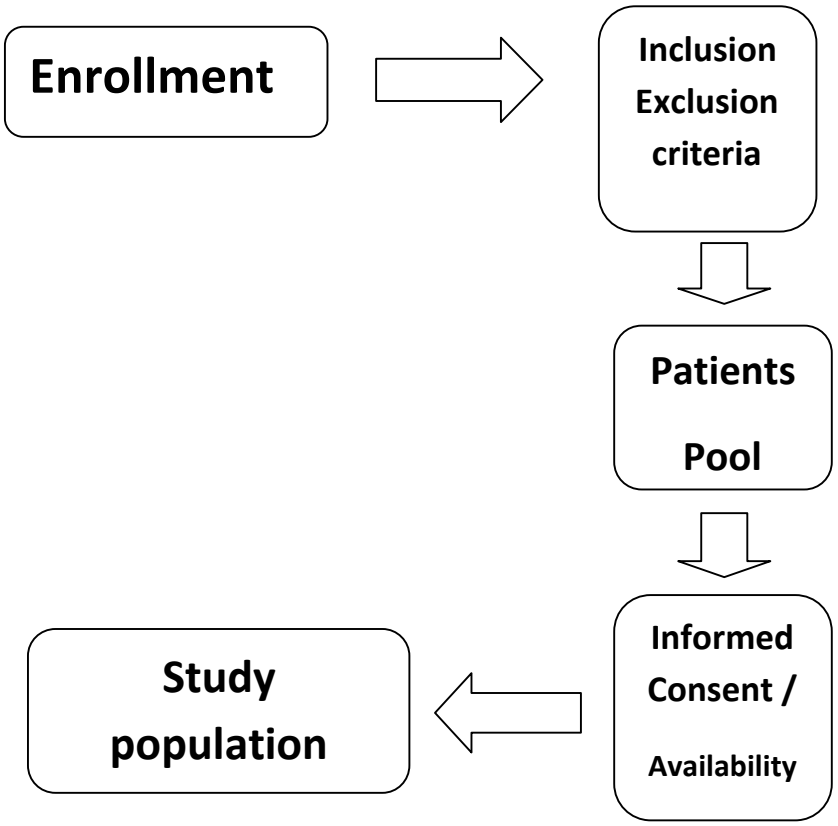


Table 1. The study flow

T 0: First meeting: starting treatment, consultation and PASI

T 1: Second meeting, after 1 week: questionnaire and consultation

T 2: Third meeting after 2 weeks: questionnaire and consultation

T 3: Fourth meeting after 3 weeks: questionnaire and consultation

T 4: Stopping the treatment after completing 4 weeks

T 5: Fifth meeting, after 5 weeks: questionnaire, consultation and PASI

4 parameters were recorded on a scale including 5 possibilities, as follow: "very low" – "low" – "medium or moderate" – " good" – "very good", and were transformed in numbers (from 1 to 5). The parameters used in this study were:

1. Compliance: how easy was the treatment to take?
2. Improvement of general feeling: how the treatment influenced your general health?
3. Skin improvement: how are you defining the degree of your skin improvement?
4. Itch decrease: how can you evaluate the improvement in your sensation of itch?

A global total score of self evaluation was calculated on the basis of the answers to the questionnaires at each meeting, for the 3 first weeks of the treatment. After a pause during the 5th week, the total score was again calculated – however this time without the two first parameters.

One should note that this score include, only for the first 3 weeks, 2 items related to the general appreciation of the general feeling and on the degree of use of this treatment by the participants, thus allowing us to define compliance. 2 other items, directly related to the efficacy of the product (action on the skin lesions and on the itch), are included in this heterogenic score and calculated for the whole study period.

Results

14 patients accepted to participate to the study. 13 patients (12 adults with psoriasis and 1 child with atopic dermatitis) were finally enrolled in this preliminary study, including 5 women and 8 men. Age ranged from 22 to 66 years; the child was 12 years old. They were all patients with a long history of the disease, from which they suffer up to 50 years (Table 2).

1. **Compliance** scores recorded were very high, except for 2 patients which were not able to follow the instructions. As well, patients recorded usually a good general feeling while taking the treatment (Graph 1).

2. Improvement on the skin lesions and the itch was found to decrease slightly after the second week and after interruption of the treatment.

3. **The global score** – indicating global improvement and including the 4 parameters recorded – showed continuous increase, and reached the level of **83.6 points**, revealing a frank success of this treatment (Graph 2).

4. The global physician appreciation determined the results as follow:

   Non responders: 4 (including 1 patient which did not take the treatment)
   Responders: **9** (including 5 patients with very good response).

   In percent: non-responders: 25% and **responders: 75%.**

5. The average modified PASI score of the 8 responders suffering from psoriasis dropped from 23 to 13 points, with an average improvement of 40.9% (15.3 to 60%) (Graph 3).

6. No rebound effect was recorded in any of the patients who stopped the treatment after the 4^{th} week. However, less improvement was found in the majority of them at week 5.

7. Adverse effects were not recorded at all during the whole follow-up of 5 weeks, giving the strong impression of a totally safe treatment.

8. All patients were very motivated and reported about good tolerance. Responders were even more enthusiastic, seeing improvement of their lesions while feeling much better.

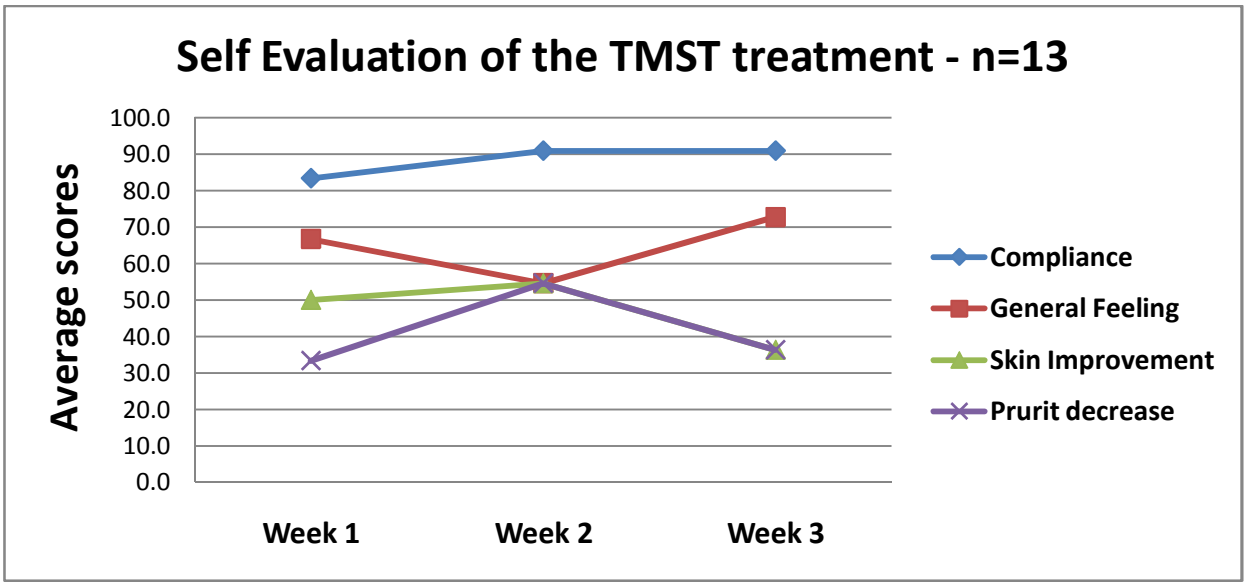
9. One of the participants entered the study while already taking regularly twice a month an injection of a new drug for psoriasis and psoriatic arthritis. The treatment allowed postponing the scheduled injection for 2 weeks more, and she received it one month after the last one. Such a delay was possible because of the obvious improvement of the skin lesions but also because of the reduction of the pain in the joints.

10. Other sufferers from Psoriatic Arthritis mentioned also an improvement in morning stiffness and pain intensity; however, this study was not programmed for such an evaluation. Moreover, the small number of patients suffering from joint involvement (4 participants) does not allow concluding about the possible effects of the treatment on the joints.

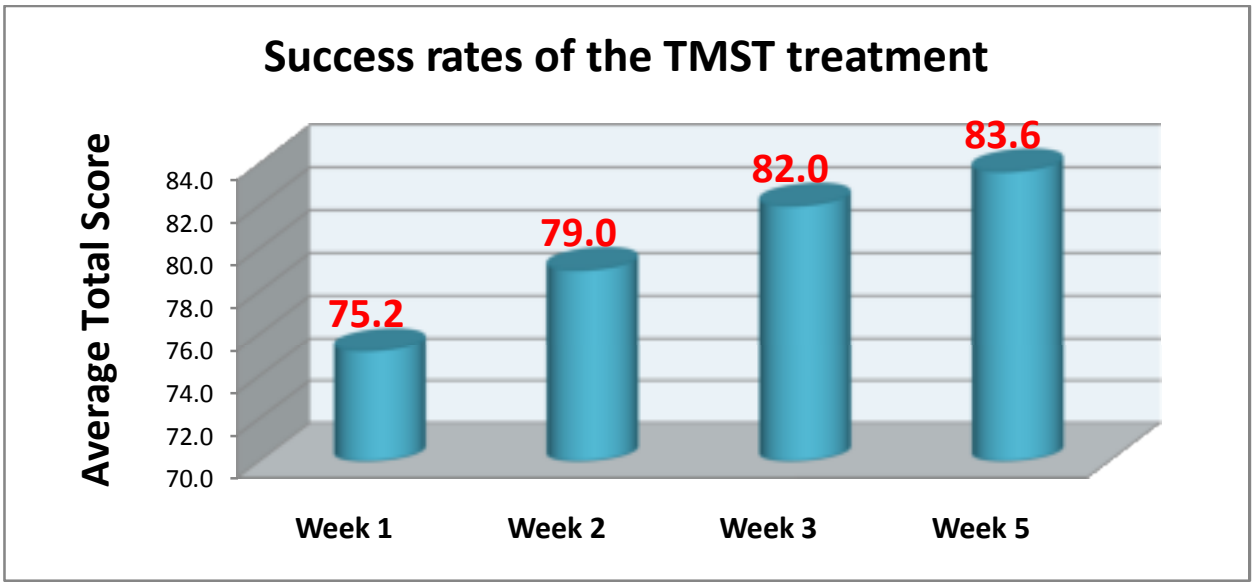
Table 2. Demographic data and disease features

Study Nr.	Name Initials	Gender	Age (Y)	Age of disease (Y)	Systemic Treatment	Modified PASI	Disease
1		F	34	29	Yes	25	PS Vulgaris Capitis Corporis Psoriatic Arthritis
2		F	38	4	No	20	PS Vulgaris Capitis Corporis
3		F	50	29	Yes	17	PS Vulgaris Capitis Corporis Psoriatic Arthritis
4		M	56	45	No	-	PS Vulgaris Capitis Corporis
5		M	66	50	No	-	PS Vulgaris Capitis Corporis
6		M	25	14	No	35	PS Vulgaris Capitis Corporis Psoriatic Arthritis
7		M	35	18	No	28	PS Vulgaris Capitis Corporis Psoriatic Arthritis
8		M	22	10	No	15	PS Vulgaris Capitis Corporis
9		M	34	26	No	13	PS Vulgaris Capitis Corporis
10		M	50	32	No	28	PS Vulgaris Capitis Corporis
11		M	40	15	No	-	PS Vulgaris Capitis Corporis
12		F	38	24	No	-	PS Vulgaris Capitis Corporis
13		F	12	11	No	-	Atopic Dermatitis

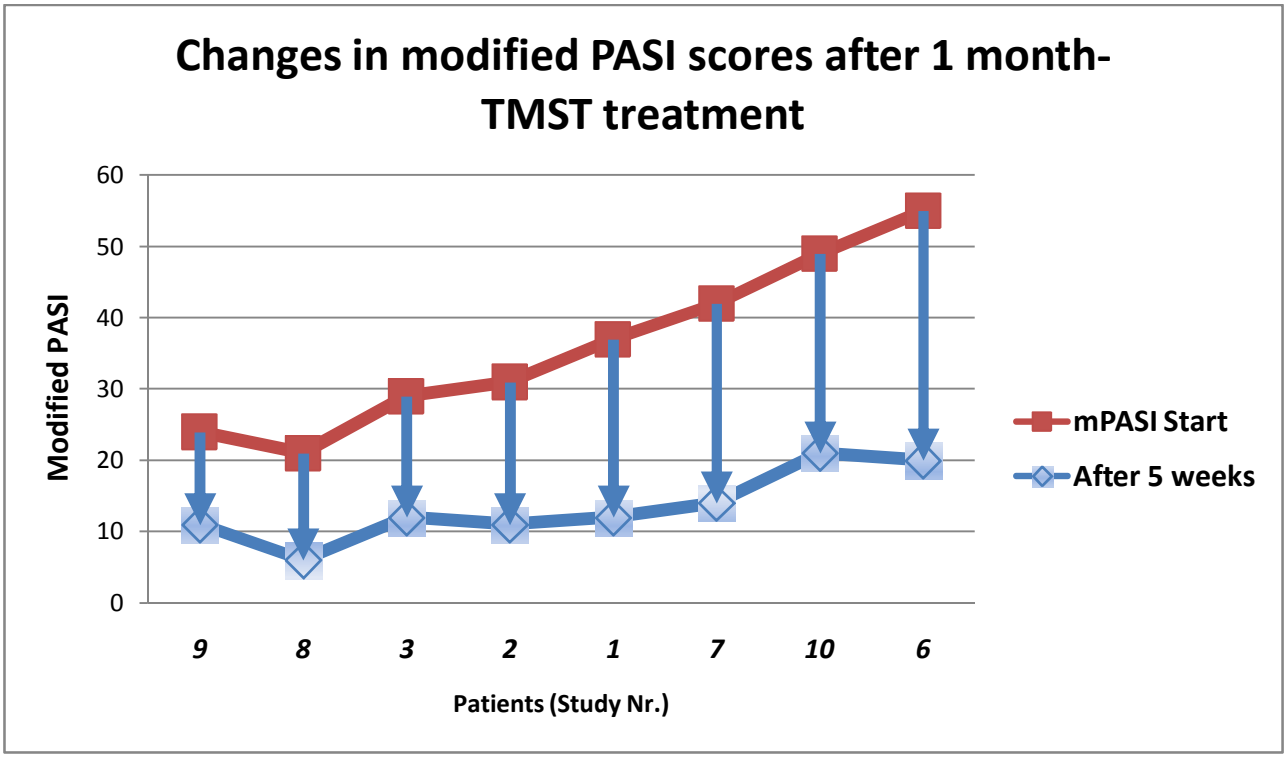
Graph 1. Evolution of the 4 parameters recorded



Graph 2. Global evaluation of the TMST success rates



Graph 3. Modified PASI scores for the 8 responders patients suffering from psoriasis before and after treatment



Discussion

The first issue - and maybe the most important one – that one can raise after completing such a preliminary study is: may the T.M.S.T. method have a place in the treatment of Psoriasis? The answer is – Yes, surely.

Our general impression was that this combination of methods is a good way to improve both clinical symptoms and general health of patients suffering from a chronic skin disease like psoriasis.

The important issues to remember from this small and very first study are:

1. None of the participants had to stop the treatment
2. No side effects were reported
3. 75% of participants were "responders"
4. Improvement appeared in the "responders" relatively fast – after 2 weeks, and continued to increase with time
5. One-week pause did not induce significant worsening.

All the participants reported at each meeting an increased energy and a better feeling. Gastro-intestinal disturbances were often "healed" during the treatment and many reported also improvement in their Quality of Life. Finally, we should highlight the fact that the "non-responders" group was composed by patients who were not able to follow correctly the diet, for many reasons (social stress for example).

Of course, some points remain still to make clear, and here we can highlight them:

1. The TMST treatment had a good impact on the body plaques, the itch and the scales but less on the scalp involvement
2. The extent of the psoriasis lesions was not influencing the improvement reached by this method
3. Some patients did not react at all, so that we can ask if the treatment is suitable for all the clinical forms of psoriasis
4. One-month therapy seems to be too short for allowing total clearance and a long term remission

Our conclusions are as follow:

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Annex 1. The TMST treatment from Mineral Mor Ltd.

Why T.M.S.T.?

Many factors are suspected as causing psoriasis by the medicinal world. These factors have been thoroughly researched, but one question mark stands above all as for the best solution. The despairing search for a "magic ointment" that will heal the wounded skin and ease the pain leaves most patients without an answer or hope. Focusing of an external symptomatic treatment is not the answer in this case (as in many other chronic diseases); nevertheless, conventional medicine refuses to look at any other option and therefore avoids the option of true healing.

Shedding a different light on psoriasis

The natural holistic approach looks at the external processes happening in the body as a warning sign, signaling to look inside and examine where the source of the problem lies. Using these distress signals, the wounded tissue or system directs us to a much more fundamental problem which exists deep inside our body. In this case, the reaction of the immune system initiates a chain reaction of autoimmune processes, which lead to the appearance of the variety of symptoms characterizing psoriasis.

The effective treatment mechanism

Psoriasis is known as a complex disease with a complicated and unique mechanism. The character of the disease is deep and radical, therefore, the treatment must act in the same manner – be deep and radical, precise, with fast and effective results. Such treatment will work in different levels at the same time, to enable true healing for the short and the long term. Therefore, we require a **focused and effective** healing method, a tested and proven method for all cases of psoriasis, even the most sever ones. **T.M.S.T.** is a unique treatment method, focused on solving the problem from the source. **T.M.S.T.** does provide fast and effective external solution, nevertheless, the treatment is mostly aimed at the internal source of the problem. This treatment method acts on several central body systems which came out of balance – the digestion system, the immune system, and the liver. According to our method, balancing these faulty systems, systemic healing and maintaining the results for the long term will provide the patient with a healthy lifestyle, psoriasis-free.

System principals

T.M.S.T. is composed of a few components that act together in complete synergistic balanced to solve the problem. Only an accurate combination of these components will enable full healing. **A combination** of medicinal herbs, fatty acids, ascorbic acid, vitamins and minerals acts in the most efficient manner to **restore balance** to the body systems, the tissues and the organs, via support, nutrition and balance of the metabolic, nerve, hormonal and immune activity. Each one of these components is essential to the systemic treatment.

T.M.S.T. in tabs and liquid contains, among others, medicinal herbs that allow an improvement to the digestion system and the liver functioning, cleansing the liver, supporting essential physiological systems, balancing the nerve system, decreasing the metabolic burden, delaying inflammatory processes, encouraging toxins discharge and reducing the excessive cell growth. The medicinal herbs nourish the different body systems that came out of balance and balance them.

T.M.S.T. contains, among others, fatty acids that assist in regulating and moderating of inflammatory processes characterizing psoriasis. EPA fatty acid is well known as significantly lowering leukotriene levels (inflammation triggers). In addition, researches show that a high dosage of EPA allows improving the skin condition and mitigating the severity of the problem. Furthermore, Omega-3 fatty acids serve as a raw material for a variety of chemical derivatives that mitigate the immune reaction of the body and allow the transfer of cell signals and nerve transmissions.

T.M.S.T. VC contains, among others, ascorbic acid, which is essential to the normal creation of collagen, skin repairing, healing wounds and building tissue, assists in wound cicatrization and decreasing the tendency for inflammations and infections in the skin. In addition, ascorbic acid serves as a potent antioxidant, neutralizes oxygen free radicals and heavy metals, reinforces and supports the immune system, encourages normal functioning of the immune system and improves the body's ability to function under stress and anxiety.

T.M.S.T. : a unique combination of vitamins and minerals that contribute to regulating and focusing on the complex reaction of the immune system. The vitamins and minerals act together, through the different influence mechanisms, to provide metabolic and mental balance, bridge nutritional gaps, normalize nerve transmission and nourish the different body systems.

T.M.S.T. cream in completely natural; cortisone and steroid free; extremely concentrated; aloe-vera dead-sea minerals, essential oils and medicinal herbs based. The unique compound of the crème efficiently treats defective and wounded skin characterizing acute chronic skin diseases. The medicinal herbs and the essential oils in the cream encourage tissue restoring, restore and nourish salivary tissues, alleviate cases of itching and accelerate the healing process. **T.M.S.T. cream** penetrates the skin layers, nourishes, restores, mends, protects and calms the skin while enabling significant fast relief. The cream absorbs quickly and helps the skin heal efficiently.

Why T.M.S.T.?

- A completely natural healing method, with no side effects.
- Cortisone, steroid and other chemical substances free.
- Focused, deep, systemic heeling.
- Long term and short term fast recovery.
- Treats even the most acute cases.
- Hundreds of success stories.

Nutrition with T.M.S.T.

Logic says we need food to live and survive. Nevertheless, the question is whether the food we consume nowadays is appropriate? Does it really nurture and enrich our body with the necessary nutrients, or does it harm us and impose health hazards? Nowadays, we consume much more industrialized food, chemically processed in order to have longer shelf live and avoid decay, food with industrialized fats that allow preservation, food lacking any nutritious value. These harmful foods usually carry strong, dominant addictive taste. It is very much recommended to be aware of the components in the foods we consume, especially when coming to treat psoriasis.

T.M.S.T. nutritional recommendations are accurate and precise, in order to allow the body systems to normally metabolize, digest, absorb and assimilate the food components, while neutralizing any inflammatory or allergenic factor that might interfere with the healing process. Rigorously sticking to the detailed diet given as part of the treatment, allows the body to recover quickly, for the short and the long term.

Alongside advises for healthy lifestyle and proper wise nutrition, combined with topical treatment, T.M.S.T. assists in alleviating and calming down the pathological activity in the different body areas.

Annex 2. Informed Consent form

<u>אני החתום מטה</u>:

שם פרטי ומשפחה:	
מספר תעודת זהות:	
כתובת:	טלפון / נייד:

א) מצהיר/ה בזה כי אני מסכים/ה להשתתף בניסוי רפואי, כמפורט במסמך זה.

ב) מצהיר/ה בזה כי איני משתתף בזמן חתימת מסמך זה, בניסוי רפואי אחר הכרוך בשימוש במוצר מחקר כלשהו, וכי אני מתחייב/ת לא להשתתף בכל ניסוי רפואי אחר הכרוך בשימוש במוצר מחקר במשך כל תקופת ניסוי זה.

ג) מצהיר/ה בזה כי הוסבר לי על-ידי:

שם החוקר/חוקר המשנה המסביר: דר' מרקו הררי / רינה קרקובר

1. כי לחוקר הראשי ולחוקרי המשנה אין[1] זיקה[2] ליוזם הניסוי[3]. החוקר הראשי מקבל תגמול עבור בדיקות משתתפי המחקר, עיבוד סטטיסטי של הנתונים ועריכת סיכום המחקר בלבד.

2. כי הניסוי הרפואי נערך בנושא:
<u>השפעה של טיפול משולב "TMST" על מחלת הפסוריאזיס</u>

3. כי אני חופשי/ה לבחור שלא להשתתף בניסוי הרפואי, וכי אני חופשי/ה להפסיק בכל עת את השתתפותי בניסוי, כל זאת מבלי לפגוע בזכותי לקבל את הטיפול המקובל.

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[1] מחק את המיותר

[2] קשר של העסקה בשכר, או קשר מסחרי או עסקי, או קשר משפחתי או אישי, וכל קשר אחר, לרבות קשר של כפיפות בעבודה, שיש בו כדי לעורר חשש לקיום ניגוד עניינים או תלות, ולמעט החזר הוצאות או תשלום עבור השתתפות בוועדות לפי נוהל זה.

[3] אם החוקר הראשי הוא גם יוזם הניסוי, יש לציין זאת במפורש.

4. כי במקרה של מילוי שאלון – אני רשאי/ת שלא לענות על כל השאלות שבשאלון או על חלק מהן.

5. כי מובטח לי שזהותי האישית תשמר סודית על-ידי כל העוסקים והמעורבים במחקר ולא תפורסם בכל פרסום, כולל בפרסומים מדעיים.

6. כי יש כיסוי ביטוחי הולם של החוקרים, הרופאים והצוות הרפואי העוסקים בניסוי הקליני מפני תביעות שיוגשו ע"י משתתפים בניסוי הקליני ו/או תביעות צד ג' הקשורות עם הניסוי הקליני בין בתקופת ביצוע הניסוי ובין לאחריו. אין באמור כדי לפגוע בזכויותיי על פי כל דין.

7. כי מובטחת לי נכונות לענות לשאלות שיועלו על-ידי וכן האפשרות להיוועץ בגורם נוסף (לדוגמא רופא-משפחה, בני משפחה וכו'), באשר לקבלת החלטה להשתתף בניסוי הרפואי ו/או להמשיך בו.

8. כי בניסויים רפואיים בהם משתתפות נשים בגיל הפוריות, במקרה של הריון במהלך הניסוי הרפואי, האישה תקבל ייעוץ (על-ידי החוקר) לגבי השפעות שייתכנו על העובר ולגבי גורל ההריון, כולל האפשרות של הפסקת ההריון.

9. כי בכל בעיה הקשורה לניסוי הרפואי אוכל לפנות לד"ר מרקו הררי / רינה קרקובר מספר טלפון/משיבון: 4704-588-050 , 4323-559-054, 3117-997-08 , בכל שעות היממה.

ד) הנני מצהיר/ה כי נמסר/ה לי מידע מפורט על הניסוי הרפואי, על פי הנושאים המפורטים להלן:

1. מטרות הניסוי;
2. המספר בקירוב של המשתתפים בניסוי הרפואי;
3. התקופה הצפויה למשך ההשתתפות בניסוי;
4. שיטות: תיאור מוצר המחקר, תיאור ההליכים השונים במשך תקופת הניסוי (טיפול ומעקב), תוך הבחנה ברורה בין ההליכים המחקריים לבין ההליכים המקובלים ברפואה; ציון הסיכויים של המשתתף לקבל כל אחד מהטיפולים המוצעים בניסוי (כולל פלצבו, במידה שקיים);
5. היתרונות הצפויים למשתתף או לאחרים, כתוצאה מהניסוי;
6. הסיכונים הידועים ו/או אי-הנוחות שניתן לחזותם למשתתף במחקר;
במידה שיש בניסוי הרפואי סיכון למשתתף - הסבר על הטיפול הרפואי שיקבל במקרה של פגיעה בבריאותו והאחריות לנתינתו;
7. נסיבות בהן עלולה השתתפותו בניסוי הרפואי להיפסק בהחלטת החוקר או היוזם;
8. לפי העניין, החוקר ימסור למשתתף מידע על תוצאות רפואיות אפשריות של החלטת <u>המשתתף</u> על הפסקת השתתפותו בניסוי הרפואי לפני סיומו;
9. הסבר על טיפולים חלופיים, ועל יתרונותיהם וחסרונותיהם, באם ישנם כאלה, למשתתף;
10. מידע רלוונטי אחר (כפי שנמסר על-ידי יוזם הניסוי):

ה) הנני מצהיר/ה בזה כי את הסכמתי הנ"ל נתתי מרצוני החופשי וכי הבינותי את כל האמור לעיל. כמו-כן, קיבלתי עותק של טופס הסכמה מדעת זה, נושא תאריך וחתום כדין.

ו) עם חתימתי על טופס הסכמה זה, אינני מתיר ליוזם הניסוי הרפואי גישה ישירה לתיקי הרפואי, לשם אימות שיטות הניסוי הרפואי והנתונים הקליניים. אבל אני מתחייב/ת למסור כל המידע הנחוץ למבצע המחקר.

שם המשתתף/ת בניסוי הרפואי	חתימת המשתתף/ת בניסוי	תאריך

במקרה הצורך[2]

שם העד הבלתי תלוי	מספר תעודת זהות	חתימת העד	תאריך

<u>הצהרת החוקר/חוקר המשנה</u>:

ההסכמה הנ"ל נתקבלה על-ידי, וזאת לאחר שהסברתי למשתתף/ת בניסוי הרפואי כל האמור לעיל וכן וידאתי שכל הסבריי הובנו על-ידו/ידה.

שם החוקר/חוקר המשנה המסביר	חתימתו	תאריך

[2] במקרה שהמשתתף בניסוי, או נציגו החוקי, אינו מסוגל לקרוא את טופס ההסכמה מדעת, עד בלתי תלוי חייב להיות נוכח במשך ההסבר על מהות הניסוי הרפואי. לאחר שהמשתתף או נציגו החוקי הביע את הסכמתו בעל-פה להשתתפות בניסוי, העד יחתום על טופס ההסכמה, תוך ציון תאריך החתימה.

Annex 3. Weekly evaluation form

Mineral Mor Ltd. TMST Preliminary Study

Evaluation Form **Study Nr. ____** **After Week #: ____**

A. Please evaluate the real use of the treatment and its influence on 3 parameters as follow during the last week:

	Very Low	Low	Moderate	Good	Very Good
1. Level of use	________	___	_________	___	_________
2. General Feeling	________	___	_________	___	_________
3. Skin Improvement	________	___	_________	___	_________
4. Itch	________	___	_________	___	_________

B. **Can you report on side effects?** N0 YES:

C. Any other remark or comment?

____
____
____

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D. Investigator impression:

____
____
____

E. Concomitant treatment / Treatment changes:

____
____
____

F. Other remarks:

Date: _______________________ **Signature: _________________________________**
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