# THE EFFICACY OF 7% KAEMPFERIA PARVIFLORA CREAM FOR THE TREATMENT OF MELASMA

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**ARTICLE HISTORY**
**Received:** 7 April 2025 **Revised:** 21 April 2025 **Published:** 6 May 2025

## ABSTRACT
Melasma is a common facial skin problem, characterized by irregular hyperpigmentation on both sides of the face. Since people nowadays pursue the beauty of skin and its health, melasma has become a big concern for the quality of life and mental health of the affected persons. It has a huge impact on the confident level during social communication**.** Many factors are liable for the occurrence of melasma including genetics, exposure to UV radiation, hormonal imbalance, pregnancy, and some medicines such as phenytoin. The aim is to decrease melanocyte proliferation and elevate the breakdown of melanin in the treatment of melasma. There are many available and effective options for curing melasma. Some natural extracts from medicinal *herbs* are used for the treatment of melasma because of their proven improvement in melasma. They are affordable, *and* consumer-friendly. *Kaempferia parviflora* is also widely known as "Thai ginseng". Its origin was in *the* northeast of Thailand, and it can be found plentifully in Malaysia and Thailand. *Kaempferia parviflora* has been long used as herbal folk medicine. Based on safety and efficacy, *Kaempferia parviflora* has been chosen in Thailand as one of the top 5 medicinal products and also has the target to produce more income to the country. Kaempferia parviflora extract can reduce oxidative stress and also has impressive anti-inflammatory and anti-tyrosinase benefits. We will focus on the anti-tyrosinase activity of 7% *Kaempferia parviflora* and study its potency in treating melasma as a facial cream.
**Keywords:** Melasma, *Kaempferia Parviflora*, Medicinal Product, Thai Ginseng

**CITATION INFORMATION:** Mon, T., & Rummaneethorn, P. (2025). The Efficacy of 7% *Kaempferia Parviflora* Cream for the Treatment of Melasma. *Procedia of Multidisciplinary Research, 3*(5), 33.

# INTRODUCTION

Melasma is a common facial skin problem, characterized by irregular hyperpigmentation on both side of the face. (Bagherani et al., 2015). “Melas” from melasma means dark coloration (Bandyopadhyay, 2009). Another name for melasma is “chloasma” indicating “mask of pregnancy”. (Handel et al., 2014). Melasma is classified as epidermal, dermal, or mixed type (Gilchrest et al., 1977) .Many factors are liable in the occurrence of melasma including genetics, exposure to UV radiation, hormonal imbalance, pregnancy and some medicines such as phenytoin. (Sarkar et al., 2014). Curation of melasma is quite exigent for many of its aspect remain in the grey area. (Shweta et al., 2014).

The aim is to decrease the melanocyte proliferation and elevate the breakdown of melanin in the treatment of melasma. (Cestari et al., 2009).There are many available and effective options in curing melasma. Some natural extract from medicinal herbs such as coffee berry and licorice are used for the treatment of melasma because of their proven improvement in melasma. They are affordable, consumer friendly. (Cadiz-Gurrea et al., 2017). Tranexamic acid, azelaic acid, ascorbic acid, arbutin are also popular alternatives in treating melasma. (Sarkar et al., 2014). There are furthermore options such as laser and light therapies and chemical peeling. (Shankar et al., 2014).

*Kaempferia parviflora is* also widely known as “Thai ginseng”. *Kaempferia parviflora* has been long used as herbal folk medicine. Based on safety and efficacy, *Kaempferia parviflorahas* been chosen in Thailand as one of the top 5 medicinal products and also has the target to produce more income to the country. (Chuthaputti et al., 2013). *Kaempferia parviflora* extract can reduce oxidative stress and also has impressive anti-inflammatory and anti-tyrosinase benefits. (Amic et al., 2007). We will focus on the anti-tyrosinase activity of *Kaempferia parviflora* and study its potency in treating melasma as a facial cream.

# LITERATURE REVIEWS

Melasma is a common acquired hyperpigmentation disorder that affects up to 30% of child-bearing women in certain populations. (Thierry et al., 2017) It is characterized by asymptomatic light to dark brown macule and patches with symmetrical distribution and irregular borders on sun exposed areas. (Rajanala et al., 2019). Melasma comes from "melas" which means dark color (Bandyopadhyay, 2009), also known as "melasma", which means "mask of pregnancy". (Handel et al., 2014). The effects on the quality of life of affected individuals are well documented and so new treatment strategies are needed. (Thierry et al., 2018). It can also disrupt facial morphology as an important fact of self-confidence and dealing with others. Compared with men, most patients were women (Jiang et al., 2018).

**Epidemiology**

Melasma is a common pigment abnormality that often prompts people to seek dermatological care. Its population prevalence varies by ethnic composition, skin phototype, and sun exposure. Race is one of the triggers of melasma. (Ortonne et al., 2009). Melasma and sex are the most common link, with women being 7 to 9 times more likely than men. In 40-50% of female patients, the disease is triggered by pregnancy or the use of oral contraceptives. Melasma occurs in 8% to 34% of women taking COCs (combined hormonal oral contraceptives), which have also been reported after hormone replacement therapy. (Ana et al., 2014).Pregnancy is also strongly associated with melasma (50-70%). Research shows a significant reduction in prevalence after age 50, likely due to menopause and the reduction in melanocyte number and activity that occurs with aging. (Videira IF et al., 2013).

**Classification and clinical presentation**

Melasma can be mainly classified into centrofacial, malar and mandibular types. Comparing these, the most common site is centrofacial area while mandibular is the least common area. (Lynde et al., 2006). Melasma can be subdivided into 4 types based on the primary pigment

location: epidermal, dermal, mixed or indeterminate types (e.g. in a patient with very dark skin pigmentation.

**Pathophysiology**

The pathophysiology of melasma is still not clearly understood (Demirkan et al., 2017). Many risk factors like exposure to sunlight and hormonal imbalance have been found to have impact on the occurance of melasma (Kim et al., 20212). Increased melanin production in melasma is well established. Individuals affected with melasma have thicker and curler elastic fibers compared to normal skin in histology. (Rajanala et al., 2019). Melasma skin also has higher number of mast cells than unaffected skin. (Videira IFS et al., 2013). Histamine released from mast cells binds to H 2 receptor and activates the tyrosinase pathway inducing melanin synthesis. (Yoshida M et al., 2000). Abnormality in basement membrane plays a role in melasma pathology. Damage from UV exposure activates matrix metalloproteinase 2 and 9 (MMP2 and MMP9) to degrade collagen type IV and VI in the basement membrane. (Kwon S et al., 2016). Hormonal influence has been shown to play a role in production of melanin.

Melanosomes are synthesized by epidermal melanin unit and then are transferred adjacent keratinocytes bi-directionally throughout dendrites which are structures resembles the arms. A membrane which is unique organelle in that biosynthesis of melanin occurred as a group of cells cap covering the keratinocyte's nucleus is the melanosome (Bertrand et al., 2020).

***Kaempferia parviflora* rhizome extract**

*Kaempferia parviflora* also known as "Thai ginseng" (KP) is a medicinal plant, especially in Malaysia and Thailand. It is also pronounced Krachaidam in Thai. Also known as black ginger, it is popular as a health-promoting herb and is traditionally used as a folk remedy for urinary tract infections, fever, cough, asthma, and sexual dysfunction, especially in men (Saokaew et al., 2016). *Kaempferia pariflora* is one of the main products that increase the GDP of the country. However, clinical studies in humans are still limited (Chuthaputti A, 2013).

**Biological activity of Kaempferia rhizome extract**

**Anti-tyrosinase activity:** In one study, the compounds 5-Hydroxy-7,3,4-trimethoxyflavone, 5,7,3,4-Tetramethoxyflavone, 5,3-dihydroxy-3,7,4-trimethoxyflavone and 5-hydroxy-3,7, 3,4-tetramethoxyflavone has anti-tyrosinase activity, can inhibit TRP 1 and 2 mRNA, resulting in melanin production.

**Antioxidant activity:** *Kaempferia parviflora* contains a variety of flavonoids that play an important role as free radical scavengers. (Yenjai et al., 2004). Several studies have shown the potential of flavonoids to have antioxidant activity (Pietta, 2000).

**Anti-aging activity:** Skin aging such as intrinsic type is mainly caused by intracellular stress. The main reasons are cellular senescence and mitochondrial dysfunction (Lo´pez-Ot´ın et al., 2013). Mitochondrial homeostasis is associated with anti-aging (Gomes, Price, Ling, Moslehi, Montgomery, & Rajman, 2013). In one study, it slowed the intrinsic skin aging process by inhibiting cellular aging and mitochondrial dysfunction. *Kaempferia parviflora* prevents the formation of wrinkles and promotes the production of collagen and elastin. (Ji-Eun et al., 2017).

**Regarding toxicity**: one study showed that 15% of the saffron was free of inflammation and swelling in the skin after 48 hours of use in rats. Histological examination showed no difference in the morphology of the skin of the test and control rats, indicating that the transdermal administration is safe. In addition, another study showed that LD50**.***Kaempferia parviflora* powder exceeds 13.33 grams per kilogram of body weight. At this dose, no abnormal histopathological changes were seen in various internal organs. (Chivapat et al., 2010). A chronic toxicity study in rats at 5, 50 and 500 mg/kg/day for 6 months showed that it did not produce any signs of drug toxicity and did not show any signs of drug toxicity in various any histopathological changes were induced in the study organ. The dose is 500 mg/kg, which is about 100 times higher than the dose used in humans. (Sripanidkulchai et al., 2019). Finally,

the study focused on the treatment of melasma. The findings will support the diagnosis and treatment of melasma using *Kaempferia parviflora* as an alternative therapy for melasma.

## RESEARCH METHODOLOGY

20 subjects (age between 30 to 65 years with Fitzpatrick Skin type III-V with melasma) who matched with all criteria will be enrolled. Volunteers are thoroughly explained about the research purpose, detail procedure and anticipated risk and benefits of the study. Participants are requested to fill the form and sign the informed consent. Take history about participants' general information, previous medical history and any history related to the study. Before the study, Patch test is tested on the arm of each volunteer with waterproof patch containing 0.1 ml *Kaempferia parviflora* for 24 hours. Exercise, extreme activities, long duration sun exposure should be avoided. Re-examination is taken for any response for 48 to 96 hours. Volunteers with positive patch test will be excluded as exclusion criteria.

Participants with positive patch test results from score ++ and above were excluded from the study. 7% *Kaempferia parviflora* extract cream will be applied to the whole two times per day for 12 weeks. Moreover, volunteers will be given mild facial cleaning gel and sunscreens SPF 50, PA+++. MASI score and mexameter® MX18 measurement will be evaluated at baseline, 4th, 8th and 12th weeks along with photography by VISIA®. The photograph of volunteers with VISIA® will be captured in 3 different positions (left, right and center) at 0, $4^{th}$, $8^{th}$ and $12^{th}$ week accordingly. Mean melanin index was assessed by the investigator using the Mexameter®, and the scores were calculated at weeks 0, 4, 8, and 12. Melanin index was measured on both sides of the face where there's marked hyperpigmentation. Side effects and satisfactory score of the volunteers will be observed and evaluated by three dermatologists and will be recorded throughout the study.

**Clinical evaluation**: In clinical, the modified MASI score is used to assess the severity level of melasma. The system uses mainly two parts: area and darkness. To estimate the area (A), it must be scored out of a total of seven. 0 means not involved, 1 means less than ten percent of the affected area, 2 means ten to twenty-nine percent of the area, 3 means thirty to forty-nine percent, and 3 means percentage between 30-39, 4 is 50 to 55 percent affected area, 5 is 70 to 89 percent affected area, 6 is 90 or more percent affected area. To estimate darkness (D), the scale is zero to four. 0 is normal, 1 is naked eye hyperpigmentation, 2 is mild, 3 is moderate, and 4 is severely dark skinned. Therefore, a modified MASI score is measured at each visit.

## RESEARCH RESULTS

Twenty healthy volunteers aged 30-65 years with Fitzpatrick skin type III to V who have melasma and compatible with all the inclusion criteria were registered. All twenty volunteers complete this study.

The demographic of the participants in this study are shown in Table 1. There were total participants 20 individuals, with distribution of gender: 5 males and 15 females. A total of 20 participants were initially enrolled in the study. Analyses were conducted with data from the 20 participants who completed the study. The average age of the participants was 45.1±8.1 years. The participants were 4 business owner (25%), 7 housewives (35%) while the remaining 9 were employees (45%). No participant has an underlying medical condition or photosensitivity or drug induced hypersensitivity, and none had received any treatment in the four weeks prior to the study. All 20 volunteers have sun exposure which is aggrevating factor for melasma. In terms of skin type, 14 participants had Fitzpatrick skin type III (70%), 4 had Fitzpatrick skin type IV (20%) and 2 had Fitzpatrick skin type V (10%).

**Modified Melasma Area and Severity Index (MASI)**

**Table 2** Statistical analysis of Modified MASI score that applied 7% *Kaempferia parviflora* cream.at baseline,4th ,8th and 12th week (n=20)

| | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|
| Baseline | 8.00 | 11.70 | 9.405 | 1.19 |
| 4th week | 6.90 | 10.80 | 8.96 | 1.11 |
| 8th week | 6.50 | 10.50 | 8.37 | 1.21 |
| 12th week | 6.30 | 9.30 | 7.84 | 0.95 |

p-value determined by repeated measurement ANOVA

**Table 3** Repeated measure ANOVA

| variable | d.f | F | p-value |
|---|---|---|---|
| Modified MASI score | 3 | 52.459 | 0.000 |

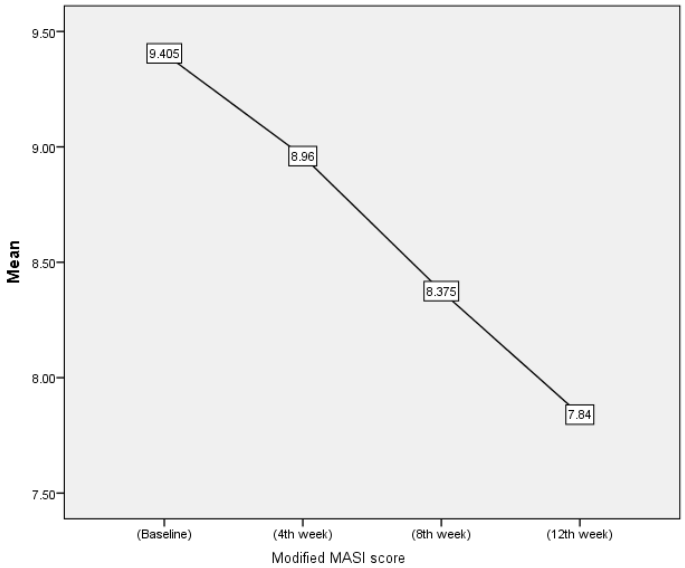


**Figure 2** Line Graph showing Modified MASI score that applied 7% *Kaempferia parviflora* cream.at baseline, 4th, 8th and 12th week.

According to results from Table 2, and Figure 2, mean of modified MASI score in 7% *Kaempferia parviflora* extract cream before the treatment was 9.405±1.19 at the baseline. The results after applying extract from were at 4th week 8.96±1.11, 8th week 8.37±1.21, and 12th week 7.84±0.95. The mean of MASI score in 7% *Kaempferia parviflora* extract cream decreased statistically significant at the level of 0.05 ($p<0.001$). The results showed clinical difference and statistically significant.

**Table 4** Multiple comparison of Modified MASI score that applied 7% *Kaempferia parviflora* cream.at baseline, 4th, 8th and 12th week

| Duration | Pair comparison | Mean difference | p-value |
|---|---|---|---|
| Baseline | 4th week | 0.445 | 0.006* |
| | 8th week | 1.03 | 0.000* |
| | 12th week | 1.565 | 0.000* |
| 4th week | Baseline | -0.445 | 0.006* |
| | 8th week | 0.585 | 0.001* |
| | 12th week | 1.12 | 0.000* |

| Duration | Pair comparison | Mean difference | p-value |
|---|---|---|---|
| 8th week | Baseline | -1.03 | 0.000* |
| | 4th week | -0.585 | 0.001* |
| | 12th week | 0.535 | 0.004* |
| 12th week | Baseline | -1.565 | 0.000* |
| | 4th week | -1.12 | 0.000* |
| | 8th week | -0.535 | 0.004* |

Note: Multiple comparison determines by the paired t test method
*The mean difference is significant at the 0.05 level.

Based on the data from above table 4, modified MASI score on 12th week is significantly higher than baseline, week 4, week 8 with p value $p < 0.05$. Moreover, differences between each week is also statistically significant with p value of <0.05.

**Melanin Index Score**

**Table 5** Statistical analysis of Melanin Index that applied 7% *Kaempferia parviflora* cream.at baseline, 4th ,8th and 12th week (n=20)

| Melanin Index | Median | IQR |
|---|---|---|
| Baseline | 215.5 | 203.25-246.415 |
| 4th week | 217.33 | 204-245.7475 |
| 8th week | 207.3300 | 198.75-229.4975 |
| 12th week | 205.5000 | 196.5825-224.83 |

**Table 6** Friedman Test

| variable | d.f | Chi-Square | p-value |
|---|---|---|---|
| Melanin Index | 3 | 41.352 | 0.000 |

According to Table 5, 6, median of Melanin Index at baseline was 215.5 with Interquartile range (IQR) 203.25 – 246.3 and at 12-week median of Melanin Index was 205.5 with IQR 196.5 – 224.8 at the level of 0.05. The results showed there is improvement of melanin index from baseline to week 12 and it is statistically significant.

**Table 7** Multiple comparison of Melanin Index that applied 7% *Kaempferia parviflora* cream at baseline, 4th, 8th and 12th week

| Duration | Pair comparison | Mean difference | Z(Wilcoxon Signed Ranks Test) | p-value |
|---|---|---|---|---|
| Baseline | 4th week | -0.866 | -.374 | 0.709 |
| | 8th week | 8.034 | -3.846 | 0.000* |
| | 12th week | 12.517 | -3.79 | 0.000* |
| 4th week | Baseline | 0.866 | -.374 | 0.709 |
| | 8th week | 8.9 | -3.79 | 0.000* |
| | 12th week | 13.383 | -3.823 | 0.000* |
| 8th week | Baseline | -8.034 | -3.846 | 0.000* |
| | 4th week | -8.9 | -3.79 | 0.000* |
| | 12th week | 4.483 | -2.091 | 0.037 |
| 12th week | Baseline | -12.517 | -3.79 | 0.000* |
| | 4th week | -13.383 | -3.823b | 0.000* |
| | 8th week | -4.483 | -2.091b | 0.037 |

Note: Multiple comparison determines by the Wilcoxon Signed Ranks Test
*The mean difference is significant at the 0.05 level

Based on the data from above table 7, mean difference on melanin index on 12th week and baseline is 12.5 which is significantly higher from the baseline. The mean difference on melanin index on 8th week and baseline showed 8.03 with p value $p < 0.05$. The results showed clinically difference and statistically significant. However mean difference on week 4 and baseline was -0.86 and p value 0.7 so statistically insignificant.

**Dermatologist evaluation score**

**Table 8** Statistically Analysis of dermatologist evaluation score compared on 4th, 8th and 12th week

| **Improvement** | **Week4** | **Week8** | **Week12** |
|---|---|---|---|
| -1 = worse | - | - | - |
| 0 = no change | 8(40%) | 7(35%) | - |
| 1 = 1-25% fairness improvement | 9(45%) | 8(40%) | 6(30%) |
| 2 = >25-50% moderate improvement | 3(15%) | 5(25%) | 13(65%) |
| 3 = >50-75% good improvement | - | - | 1(5%) |
| 4 => 75-100% excellent improvement | - | - | - |

Friedman test-Chi-square = 19.26, p = 0.0001

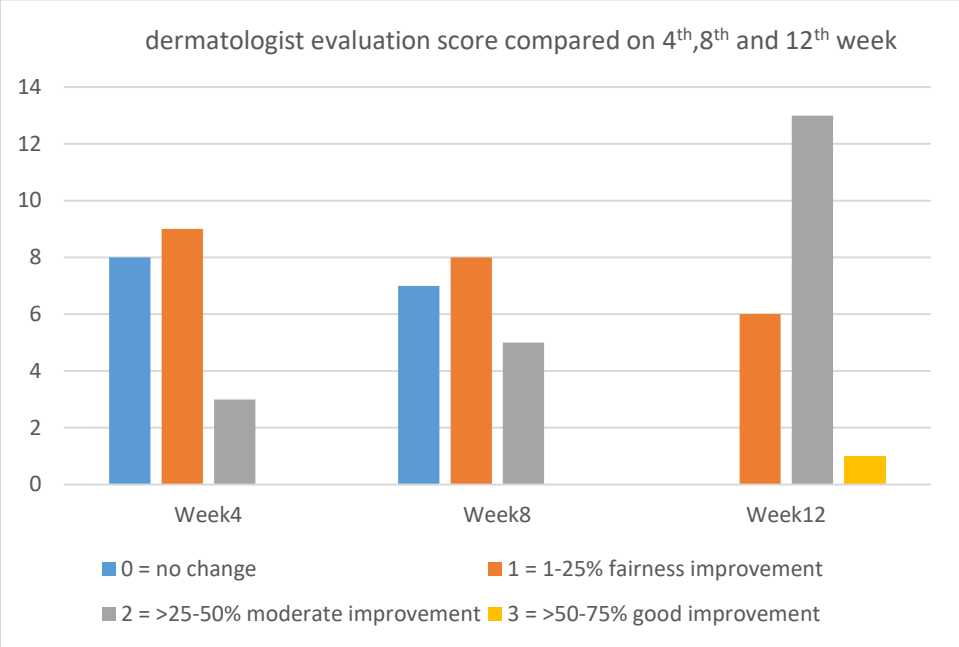


**Figure 3** presents the statistical analysis of evaluations by three dermatologists at the 4th, 8th, and 12th weeks for 7% *Kaempferia parviflora* cream.

Table 8 and Figure 3 showed for the *Kaempferia parviflora* cream on week 4, 15% of the volunteers showed no changes according to dertmatologists, 45% of subjects showed fair improvement and 15% showed moderate improvement. On Week 8, the result showed that 25% of subjects showed moderately improved, which can be compared to see that on week 12, 65% of subjects showed moderate improvement when evaluated by dermatologists. There were 35% of subjects who did not show any change until week 8 which is improved in week 12 where there is no subject evaluated as no change. On the end of the study week 12, 1 volunteer was scored as good improvement by dermatologists. Throughout the study period, no subject is tested as worsen and no subject is tested as excellent improvement.

**Patient Satisfaction score**

**Table 9** Patient Satisfaction score on 12th week

| Patient Satisfaction score | Week12 |
|---|---|
| -1=worse | - |
| 0=No satisfaction, no change | - |
| 1 = Little satisfaction | - |
| 2= Moderate satisfaction | 11(55%) |
| 3= Very satisfied | 9(45%) |
| 4= Extremely satisfied | - |

A statistical analysis for patient satisfaction for 7% *Kaempferia parviflora* extract cream revealed 45% reported "very satisfied", whereas 55%of patients experienced "moderate satisfaction at Week 12.

# DISCUSSION & CONCLUSION

Melasma is primarily recognized as one of the most prevalent types of facial hyperpigmentation which significantly impacts life quality due to its aesthetic implication. The therapeutic goal is to reduce melanin synthesis, stop melanosome production, and increase the breakdown (Cestari et al., 2009).

There is an increasing trend towards utilizing plant-derived compounds in skincare, appreciated for their natural ability to lighten skin, and are noted for their safety and cost-effectiveness. In this study, we used *Kaempferia parviflora* cream, which is significant for its strong anti-tyrosinase activity. Furthermore, the extract has been found to possess anti-inflammatory, antioxidant, and UV protection, along with skin hydration. It also offers anti-aging, anti-photoaging, anti-acne, and anti-allergic activities

In this study, the researcher studied the efficacy of 7% *Kaempferia parviflora* cream for treating melasma in an experimental before and after comparison study design. There was a total of 20 participants with 5 males and 15 females. The demographic data revealed a diverse group with an average age of 45.1±8.1 years. None of the participants reported underlying medical conditions or photosensitivity, except one individual with a food allergy, and none had undergone any treatments in the four weeks preceding the study. All participants have exposure to sunlight which has significant aggravating factors for melasma. In terms of skin type, 14 participants had Fitzpatrick skin type III (70%), 4 had Fitzpatrick skin type IV (20%), and 2 had Fitzpatrick skin type V (10%).

The data were collected by VISIA scan, modified MASI score, and Mexameter to assess skin hyperpigmentation and melanin levels for participants treated with 7% *Kaempferia parviflora*. The results showed a statistically significant reduction in skin hyperpigmentation in melasma and showed great satisfactory scores in doctors' evaluation and patient's scores. The results from research showed that *Kaempferia parviflora* cream showed great efficacy in the treatment of melasma. The study results can be summarized as follows: the topical application of 7% K*aempferia parviflora* cream did not result in any allergic reactions during the patch test, and no allergic cases were reported throughout the study. Based on this result, 7% *Kaempferia parviflora* cream might be safe for use for melasma treatment. The mean of modified MASI score in 7% *Kaempferia parviflora* extract cream before the treatment was 9.405±1.19 at the baseline. The results after applying extract from were at 4th week 8.96±1.11, 8th week 8.37±1.21, and 12th week 7.84±0.95. The mean of MASI score in 7% *Kaempferia parviflora* extract cream decreased statistically significant at the level of 0.05 ($p<0.001$). The results showed clinical difference and statistically significant. From pair t test, the result showed that modified MASI score on 12th week is significantly higher than baseline, week 4, week 8 with

p value $p < 0.05$ . Moreover, differences between each week is also statistically significant with p value of <0.05. This result suggested that the extract cream led to a great improvement in terms of modified MASI score for melasma treatment by 12th week when compared to modified MASI score from baseline and each week also showed significant improvement.

According to Friedman test for Melanin index, median of Melanin Index at baseline was 215.5 with Interquartile range (IQR) of 203.25 – 246.3, and in the 12th-week median of Melanin Index was 205.5 with IQR of 196.5 – 224.8 at the level of 0.05. The results showed there is improvement of melanin index from baseline to week 12, and it is statistically significant. Based on the data from Wilcoxon Signed Ranks Test, mean difference on melanin index on 12th week and baseline is 12.5 which is significantly higher from the baseline. The mean difference on melanin index on 8th week and baseline showed 8.03 with p value $p < 0.05$ . The results showed clinically difference and statistically significant. From the data, we can conclude that Mean Melanin Index score decreased significantly by 12th week in comparison to baseline.

During the 12th-week follow-up visit, three dermatologists assessed the volunteers and rated 30% fair improvement, 65% moderate improvement and 5% good improvement. From the patients satisfactory score by week 12, it revealed 45% reported "very satisfied", whereas 55%of patients experienced "moderate satisfaction. Based on this study and its results, *7% Kaempferia pariflora* cream is a safe and effective topical treatment for melasma treament. All participants tolerated the treatment well, with no reported side effects such as skin irritation, erythema, or hyperpigmentation throughout the study period. From the data, it can be concluded that *7% Kaempferia parviflora improved modified MASI score* and reduces the melanin index, likely due to the antioxidant and skin lightening properties of the compounds present in the cream.

**Suggestion for Future Research and Clinical Applications**

1) Future studies can investigate the long-term effects of *Kaempferia parviflora* cream beyond 12 weeks.

2) Comparing *Kaempferia parviflora* cream with other anti-aging ingredients could clarify its relative effectiveness.

3) The potential of combining this cream with other treatments like injections and lasers should be explored more.

**Conclusion**

Based on the clinical study, it can be concluded that *Kaempferia parviflora* cream significantly reduce skin hyperpigmentation with great satisfaction. In summary, *Kaempferia parviflora* cream appears to be a safe and effective topical treatment for the treatment of melasma.

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**Data Availability Statement:** The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

**Conflicts of Interest:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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