

# Comparative Efficacy of *Amalaki Vati* and *Manjishtadi* Serum versus Tablet Limcee and Retinol Serum for Facial Rejuvenation: A Randomised Controlled Trial Research Protocol

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## ABSTRACT

**Introduction:** The ageing process begins at birth and becomes apparent as the years go by. Wrinkles and hyperpigmentation or photoaging {due to exposure to Ultraviolet (UV) radiation} are signs of ageing facial skin. Nowadays, facial ageing is a big issue, with attention being paid especially to premature ageing, facial laxity, and roughness. Therefore, the safest alternative to achieve a healthier and more radiant face is to apply herbal cosmetics.

**Need of the study:** Modern cosmetic formulations are costly as well as may cause various side effects. There are some *Ayurvedic rasayanas* and cosmetic formulations with potential effects on ageing, which have not yet been studied on face rejuvenation. Out of which *Amalaki* has antioxidant properties mentioned in the *Charaka Samhita*. *Manjishtadi taila* is mainly indicated in *Vali palita* (wrinkles), *Twak vaivarnya*, depicted in *Chakradatta samhita*. So, using *Manjishtadi* serum as a modified form can give better results in face rejuvenation. Also, no study has been done on *Amalaki vati* and *Manjishtadi* serum in terms of face rejuvenation. Hence, the present study will mitigate the empirical knowledge gap.

**Aim:** To evaluate the comparative efficacy of *Amalaki vati* and *Manjishtadi* serum versus tablet limcee and retinol serum in terms of face rejuvenation.

**Materials and Methods:** The present randomised open labelled standard control superiority clinical trial will be held at Kayachikitsa Outpatient Department (OPD), Inpatient Department (IPD) of MGACH and RC Salod (H) Wardha, Maharashtra, India and Speciality Camps from March 2025 to February 2026. Two groups will be taken, with 31 patients in each. In group A (control group), participants will be given one tablet of Limcee (500 mg) once daily, along with the nightly application of retinol serum. In group B (trial group), participants will be given one tablet of *Amalaki Vati* (500 mg) once daily, combined with the nightly application of *Manjishtadi* serum. Assessment parameters i.e., wrinkle severity scale and hyperpigmentation severity scale, will be compared before and after treatment in each group by performing paired and unpaired t-tests. A p-value of <0.05 will be considered significant.

**Keywords:** Antiageing, *Twak vaivarnya*, *Vali palita*, *Rasayana*, Wrinkle severity scale

## INTRODUCTION

The largest, most defensive organ in the body is the skin. The outer and inner layers make up the majority of its composition. It's one of the five sense organs as well. In addition to keeping the body's water and electrolyte balance in check and safeguarding the body from infections, the condition and appearance of the skin have a significant impact on well-being and general health perception. Laser rejuvenation and many other invasive procedures are made possible by modern scientific advances, but they also come with drawbacks [1]. Wrinkles and hyperpigmentation/photoaging (due to exposure to UV radiation) are signs of ageing facial skin [2]. These days, facial ageing is a major problem, with premature ageing, facial laxity, and roughness gaining particular focus. However, over the past decade, there has been a noticeable rise in demand for herbal medicines to slow down the ageing process.

Therefore, these herbal formulations may be important in promoting healthy ageing and can be used to achieve a healthier and more radiant face. In addition to possessing antioxidant qualities, *Amalaki* is the most potent of the rejuvenating (*Vayasthapak*) herbs and possesses the *Rasayan* (rejuvenation), *Ajara*, *Kantikara*, and *Ayushprada* effects [3]. The *Chakradatta Samhita* illustrates *Manjishtadi taila*, which is represented by *Twak vaivarnya* (hyperpigmentation) and *Vali palita* (wrinkles) [4]. Also, *Manjishtadi taila* is depicted in *Vrundamadhava*

*athva Siddhayoga* [5]. Serum has moisturising effect and goes deeper into the skin. Because of the unique *Rasa*, *Guna*, *Veerya*, *Vipaka*, and *Doshaghnata* in *Amalaki vati* and *Manjishtadi* serum, their ingredients have antiaging properties and may help rejuvenate the face.

According to the findings of clinical research, ascorbic acid, also known as vitamin C, fights aging by halting the loss of collagen that occurs during photoaging and lessens wrinkles and sun damage to the skin [6]. However, it has been discovered that using contemporary cosmetic formulas, such as retinol serum, significantly improves skin renewal [7]. However, they also have negative consequences of their own, like redness, irritation, burning, itching, dry skin, flaking and peeling of skin, and increased sensitivity [8]. Therefore using herbal cosmetics is the safest option to improve the complexion of your face. The prevalence rate of wrinkles, along with photodamage in the adult population, is as high as 80-90% [9]. The prevalence rate of hyperpigmentation is 50%, with more women affected (59%) [10].

## REVIEW OF LITERATURE

*Amalaki* is the most revitalising (*Vayasthapak*) plant and has antioxidant qualities. It also has the *Rasayan* effect, *Ajara*, *Kantikara*, and *Ayushprada*. Thus, *Vayasthapak*, *Jarahara*, and *Kantikara* are likewise functions of *Amalaki rasayan* in the form of *vati*. *Vayasthapaka*

denotes the drugs which rejuvenates the skin. *Amalaki* rasayan is depicted in *Charaka Chikitsasthana*, *Charaka Sutrasthana* [11], *Chakradatta Samhita rasayana adbhikara* [4], according to the *Chakradatta Samhita*, *Manjishtadi taila* is represented by *Twak vaivarnya* (hyperpigmentation) and *Vali palita* (wrinkles). Serum has moisturising effect and goes deeper into the skin. So, using *Manjishtadi* serum will be effective in face rejuvenation [12].

Ayurvedic classics provide a detailed explanation of *Jara Vyadhi*, which can be closely associated with Geriatrics. *Rasayana* therapy serves as an effective approach in promoting healthy ageing and preventing its adverse effects. *Amalaki* is the foremost herb amongst all, preventing ageing and providing longevity [13]. *Amalaki* is a powerful antioxidant herb, rich in low molecular weight hydrolyzable tannins. Its high concentration of vitamin C and flavonoids helps combat harmful free radicals that contribute to cell ageing [14]. Several studies [Table/Fig-1] indicate that *Amalaki rasayana* is effective for various lifestyle disorders, in addition to its effects on aging [15-17]. While there have been investigations into modified forms of *Manjishtadi Taila* as creams and lotions, no research has been conducted on the effectiveness of its serum form [16,17].

S. No.	Author's name	Findings	Remark
1	Bargale SS et al., [15]	N=30 To one group- One placebo capsule of 250 mg was given thrice a day for 60 days, and luke warm water was given as Anupana. To group- 10 grams of <i>Amalaki rasayana</i> , along with milk, was administered. (OD) The trial drug <i>Amalaki rasayana</i> , along with milk, has shown highly significant results in treating symptoms like insomnia, constipation, digestive weakness and haemoglobin percentage.	Small sample size. Placebo study. Symptoms of facial ageing were not studied.
2	Sha SZ et al., [16]	N=30 patients In the control group, 15 candidates were given classically prepared <i>Manjishtadya taila</i> and in study group, 15 candidates were given <i>Manjishtadya taila</i> cream. <i>Manjishtadi taila</i> showed better results in <i>Twak vaivarnya</i> .	Small sample size. Symptoms of photoaging were not studied.
3	Zama A, Chavan R. Pharmaceutico-analytical study on <i>manjishtadi taila</i> and development of its new dosage form into lotion. Doi: 10.20959/wjpps202210-23381 [17]	On undertaking this study and analysing in terms of various parameters both taila and lotion have got similar characteristic features. Lotion can be taken as an alternative to application of oil by the consumers in regard of its easy adaptability and feasibility the study was undertaken.	Non-experimental, analytical study.

[Table/Fig-1]: An overview of previous research findings on *Amalaki rasayana* [15-17].

Additionally, although Ayurvedic literature mentions the combination of *Amalaki Vati* and *Manjishtadi* serum for face rejuvenation, there have been no studies examining this specific formulation. This combination is considered a potent herbal rejuvenator for the face. Therefore, this study is planned to evaluate the comparative efficacy of *Amalaki vati* and *Manjishtadi* serum versus tablet limcee and retinol serum in terms of face rejuvenation.

#### Primary objectives:

- To evaluate the efficacy of *Amalaki vati* and *Manjishtadi* serum on objective parameters in terms of face rejuvenation.

- To evaluate the efficacy of tablet limcee and retinol serum on objective parameters in terms of face rejuvenation.
- To compare the efficacy of *Amalaki vati* and *Manjishtadi* serum versus tablet limcee and retinol serum on objective parameters in terms of face rejuvenation.

#### Secondary objectives:

- To prepare *Amalaki rasayana* in *vati* form.
- To prepare *Manjishtadi* serum.

**Null Hypothesis (H0):** *Amalaki vati* and *Manjishtadi* serum will not be as efficacious as tablet limcee and retinol serum in terms of face rejuvenation.

**Alternative Hypothesis (H1):** *Amalaki vati* and *Manjishtadi* serum is more efficacious than tablet limcee and retinol serum in terms of face rejuvenation.

## MATERIALS AND METHODS

The present randomised open labelled standard control superiority clinical trial will be held at Kayachikitsa OPD, IPD, and Speciality Camps, dated March 2025 to February 2026. IEC has given an approval letter with reference no. (MGACHRC/IEC/Jun-2024/838) and CTRI registration is done (CTRI/2024/07/070651). The subjects will be recruited after obtaining written informed consent. Throughout the study, each subject's confidentiality will be preserved.

#### Inclusion criteria:

- Participants who are willing to sign a written informed consent and participate in the research;
- Subjects will be selected without any bar of race, religion & sex;
- Age group between 20-50 years;
- Patients with premature wrinkling of the face up to grade 0-2 [18] and mild to moderate hyperpigmentation [19].

#### Exclusion criteria:

- Subjects who are allergic to any cosmetics.
- Subjects who have received a facial peel or laser treatment.
- Pregnancy, nursing and self-perceived sensitive skin.
- Patients who are not willing to avoid sun exposure during the study.

**Withdrawal criteria:** The participant will be removed from the research if any adverse effects or aggravations of symptoms arise. Then the subjects will be offered treatment free of cost till the problems subside.

#### Sample size calculation:

$$n \geq \left\{ \left( Z_{(1-\alpha/2)} \sqrt{((r+1)p(1-p))} + Z_{(1-\beta)} \sqrt{(rp(1-p) + p(1-p))} \right)^2 / \{r(p(1-p))\} \right\}$$

Where:

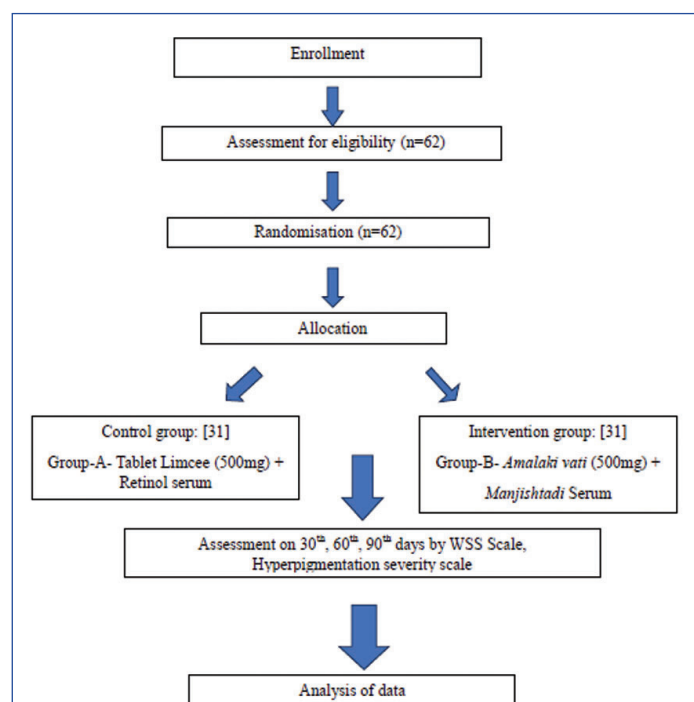
- n: Sample size per group
- p: Combined proportion, calculated as  $p = (p_1 + r * p_2) / (1 + r)$
- p<sub>1</sub>, p<sub>2</sub>: Proportions in group 1 and group 2, respectively
- Z<sub>(1-α/2)</sub>: Z-value for the selected significance level (α)
- Z<sub>(1-β)</sub>: Z-value for the selected power (1-β)
- r: Ratio of group 2 to group 1

Rate of percentage change in average depth of wrinkles proportion in ascorbic acid (Vit C) (p<sub>1</sub>): 0.089 [2]; Rate of change in average depth of wrinkles Proportion in *Amalaki vati* with *Manjishtadi* serum (p<sub>2</sub>): 0.39 (An estimated value, assuming the intervention drug is 30% superior to the control group);

Considering a 30% superiority margin- Ratio (r) (group 2/group 1): 1

- Minimum sample size needed for group 1: 31
- Minimum sample size needed for group 2: 31
- Total minimum sample size: 62

Both groups will receive treatment for 90 days. Patients will be assessed according to the objective parameters Wrinkle severity scale [18] and hyperpigmentation severity scale [19] (both pre and postintervention on baseline (30<sup>th</sup>, 60<sup>th</sup>, 90<sup>th</sup> day). The study will follow the SPIRIT guidelines and utilise a computerised random sampling technique to select a sample size of 62 participants [Table/Fig-2,3].



[Table/Fig-2]: CONSORT flow diagram.

Group	Sample size	Intervention	frequency and dosage	Anupan and route of administration	Time duration	Follow-up
A. (Control Group)	31	Tablet limcee (500mg) + retinol serum	Tablet limcee- (1 OD) Retinol Serum- (At night)	Anupan - with water route of administration- oral Local application	90 days	Day 30 <sup>th</sup> , 60 <sup>th</sup> , 90 <sup>th</sup>
B. (Trial Group)	31	Amalaki vati (500mg) + Manjishtadi Serum	Amalaki Vati - (1OD) 2. Manjishtadi Serum- (At night)	Anupan - with water Route of administration- oral Local Application	90 days	Day 30 <sup>th</sup> , 60 <sup>th</sup> , 90 <sup>th</sup>

[Table/Fig-3]: Posology chart.

## Study Procedure

**Amalaki vati:** The raw material for the preparation of *Amalaki vati* will be procured from Ayurved *Rasashala* and it will be prepared according to the reference mentioned in Charak Samhita [Table/Fig-4] [20]. The source of the raw materials will be market or authentic sources, and the drugs will be identified by the Department of *Dravayaguna* and authenticated by Ayurved *Rasashala*.

S. No.	Ingredients	Quantity
1.	Amalaki churna	1.5 Kg
2.	Amalaki bharad (raw)	2 Kg

[Table/Fig-4]: Contents of Amalaki vati.

*Amalaki vati* will be prepared by using *Amalaki bharad* to form *Amalaki churna*, by giving *bhavana* of *Amalaki swaras* to *Amalaki churna*, *Amalaki vati* of 500 mg will be prepared by air drying.

**Manjishtadi serum:** The raw material for the preparation of *Manjishtadi taila* will be procured from Ayurved *Rasashala*, and

*Manjishtadi taila* will be prepared according to the reference mentioned in *Chakradatta Samhita* [21]. The *Manjishtadi* serum will then be prepared using carefully chosen serum-specific ingredients, maintaining efficacy and Ayurvedic principles [Table/Fig-5].

S. No.	Ingredients	Quantity
1.	Aloe vera gel	4 kg
2.	Glycerin	2 kg
3.	Lypolyzed bee venom	1 kg
4.	Span 80	1 kg
5.	Tween 20	1 kg
6.	Manjishtadi taila	2 litres
7.	Sodium benzoate (preservative)	1 kg
8.	Demineralised water	QS

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7.	Sodium benzoate (preservative)	1 kg
8.	Demineralised water	QS

[Table/Fig-5]: Contents of Manjishtadi serum [13].

**Drug procurement-** Pharmaceutical business will provide Tab Limcee 500 mg manufactured in India by Abbott and Retinol serum manufactured in India by Rejusure.

**Outcomes:** Antiageing assessment scales: will be used to assess the wrinkles severity and hyperpigmentation at baseline 30<sup>th</sup>, 60<sup>th</sup> and 90<sup>th</sup> day [Table/Fig-6,7].

Grade	Definition
0	No noticeable wrinkles, no wrinkles, and a continuous skin line
0.5	Very slight creases that are still noticeable.
1	Fine wrinkles, noticeable creases and a little depression
1.5	Clear indentation and noticeable wrinkles, with a wrinkle depth of less than 1 millimeter.
2	Clear apparent wrinkles and moderate wrinkles wrinkling of 1-2 mm
2.5	noticeable and noticeable creases with a depth of more than 2 mm and less than 3 mm
3	Deep wrinkles, deep furrows, and wrinkles that are more than 3 mm

[Table/Fig-6]: Wrinkle severity scale [18].

Level	Global coverage percentage (%)	Depth of colour	Score
Mild	10-25	Light	1
		Medium	2
		Dark	3
Moderate	30-50	Light	4
		Medium	5
		Dark	6
Severe	60-95	Light	7
		Medium	8
		Dark	9

[Table/Fig-7]: Hyperpigmentation severity scale [20].

## STATISTICAL ANALYSIS

Statistical analysis will be conducted using the R software. Assessment parameters will be evaluated both before and after treatment within each group, as well as compared between groups, utilising paired and unpaired t-tests. The Gantt chart representing

the project schedule overtime has been given in [Table/Fig-8]. A p-value of less than 0.05 will be regarded as statistically significant.

#### Gantt chart:

Scholar/ Investigator	Dr. Aishwarya Suresh Rao Kadam					
Title	Evaluation of Comparative Efficacy of <i>Amalaki vati</i> with <i>Manjishtadi</i> Serum versus tablet limcee with retinol serum in terms of face Rejuvenation					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
Approval from IEC						
Review of literature						
Drug preparation						
Enrollment of patients						
Data collection						
Statistical analysis						
Thesis writing						
Submission						

[Table/Fig-8]: Gantt chart.

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