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RESEARCH ARTICLE
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A SINGLE ARM, OPEN LABEL, INTERVENTIONAL STUDY TO EVALUATE THE SAFETY, EFFICACY AND TOLERABILITY OF NEW AMRUTANJAN HEADACHE FASTER RELAXATION ROLL ON FOR PAIN RELIEF IN PATIENTS WITH MIGRAINE HEADACHE DISORDERS

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ABSTRACT:
Migraine is a chronic, recurrent neurological disorder that significantly impacts the quality of life of millions worldwide. Herbal Roll On offers a effective approach to acute migraine pain relief. New Amrutanjan Headache Faster Relaxation Roll On is an ayurvedic proprietary topical preparation formulated with a synergistic blend of Karpura (Camphor), Pudinah (Menthol), and Gandhapura Patra Taila (Oil of Wintergreen)—three well-known natural ingredients with established analgesic and counter-irritant properties. This study was designed as a single-arm, open-label, interventional trial aimed at evaluating the Safety, efficacy and tolerability of New Amrutanjan Headache Faster Relaxation Roll On in participants with migraine headache disorders.Twenty four participants with migraine headache disorders were enrolled in this study and was done for a period of 2 weeks. The enrolled patients received New Amrutanjan Headache Faster Relaxation Roll on twice or thrice daily topically for one day**.** Participants were monitored throughout the study to evaluate primary and secondary outcome measures.Participants experienced the onset of pain relief rapidly, with an average onset time of 1 minute and 49 seconds after application of the product. Among participants who achieved complete pain relief (n=10), the average time taken was approximately 22 minutes. The mean duration of pain relief following application of the New Amrutanjan Headache Faster Relaxation Roll-On was 111 minutes and 15 seconds. Pain relief was sustained for up to 60–75 minutes before gradually returning. The McGill Pain Questionnaire results confirm that New Amrutanjan Headache Faster Relaxation Roll On effectively reduced multiple dimensions of pain, not just intensity. The participants' overall satisfaction scores indicated a positive perception of pain relief following product use. 41.7% participants did not require any rescue medication, indicating that the product was effective as a standalone therapy for a substantial proportion of users.In

conclusion, the findings from this interventional study support the New Amrutanjan Headache Faster Relaxation Roll On as a safe, well-tolerated, and effective topical option for the relief of migraine headaches. Its rapid onset of action, sustained pain relief, and favorable safety profile make it a promising non-pharmacological adjunct or alternative for migraine management.

Keywords: Migraine, Headache, Herbal Roll-on, Amrutanjan, Rapid relief

INTRODUCTION:

Migraine is a chronic, recurrent neurological disorder that significantly impacts the quality of life of millions worldwide. Characterized by unilateral, pulsating headaches often accompanied by nausea, vomiting, and heightened sensitivity to light and sound, migraine presents a substantial therapeutic challenge. Conventional pharmacological treatments, while effective for many, are often associated with delayed onset of relief, medication overuse headaches, or systemic side effects, prompting the need for safer and faster-acting alternatives. [1]

Topical therapies have gained growing interest in migraine management due to their ability to provide localized, rapid relief with minimal systemic absorption. Among these, herbal and traditional formulations are especially valued for their safety profiles and multimodal mechanisms of action.[2] Herbal Roll On offers a effective approach to acute migraine pain relief , as it contain essential oils that may help alleviate nausea, anxiety, and other migraine related symptoms.[3]

New Amrutanjan Headache Faster Relaxation Roll On is an ayurvedic proprietary topical preparation formulated with a synergistic blend of Karpura (Camphor), Pudinah (Menthol), and Gandhapura Patra Taila (Oil of Wintergreen)—three well-known natural ingredients with established analgesic and counter-irritant properties.

- Karpura (Camphor) is widely used in traditional and modern medicine for its cooling, anti-inflammatory, and mild analgesic effects. It acts as a counter-irritant, producing a cooling sensation that distracts from deeper pain and improves local circulation. [4]
- Pudinah (Menthol) contains menthol, a compound that activates TRPM8 cold receptors, thereby providing a soothing effect and reducing the perception of pain. Studies have shown that topical application of menthol is effective in reducing tension-type and migraine headaches. [5]
- Gandhapura Patra Taila (Wintergreen oil) is rich in methyl salicylate, structurally similar to aspirin. It has potent anti-inflammatory and analgesic properties and is commonly used in topical formulations for musculoskeletal pain and headaches.[6]

This study was designed as a single-arm, open-label, interventional trial aimed at evaluating the Safety, efficacy and tolerability of New Amrutanjan Headache Faster Relaxation Roll On in participants with migraine headache disorders. By assessing parameters such as onset and duration of pain relief, reduction in headache intensity, and user satisfaction, this research seeks to substantiate the role of this topical herbal formulation as a safe, effective, and fast-acting option in migraine management.

Objective:

- To evaluate the safety, efficacy and tolerability of New Amrutanjan Headache Faster Relaxation Roll On for pain relief in participants with migraine headache disorders.

MATERIALS AND METHODS :

This study was conducted as a single arm, open label, interventional study in DK Elite Health Care Centre, Puducherry with the help of Ki3 Private Limited, for a period of 2 weeks. The study has been done after obtaining permission from Independent Ethics Committee - Ethique De La Nature Association (IEC approval number –EC/071/25). The development of study protocol, conduct of the study, data entry, followed by statistics and report were done in compliance with the ICH GCP, the

Quality Policies and Standard Operating Procedures set forth by the organization.

Inclusion criteria:

Participants who fulfilled the following criteria were enrolled in the study:

- Participants of either sex aged between 18 to 65 years and were able to understand written and/or verbal instructions and demonstrated readiness to comply with all study requirements, with a willingness to participate and voluntarily provide written informed consent.
- Participants who had been diagnosed with migraine-type headache (Common Migraine, Classical Migraine, Ophthalmic Migraine, or Basilar Migraine) according to the International Classification of Headache Disorders, 3rd edition (ICHD-3) criteria.
- Participants who reported a pain score of ≥ 3/10 (based on the numeric pain rating scale) during the week prior to screening and those who had experienced migraine attacks for more than one year.
- Participants whose migraine attacks, when untreated, typically lasted between 4 and 72 hours.
- Participants who had less than 15 headache days (migraine or non-migraine) per month during each of the 3 months preceding the screening visit and throughout the screening phase.

Exclusion criteria:

Participants with the following criteria were excluded from the study:

- Women of childbearing potential who were either unwilling or unable to use an acceptable method of birth control (such as oral contraceptives, other hormonal contraceptives including implants, injectable products, vaginal products, skin patches, or IUDs, or barrier methods) to avoid pregnancy during the study period.
- Participants who were pregnant, lactating, unable to distinguish other types of headaches from migraine and those with a history of resistance to sumatriptan, or non-response to two or more other triptans, defined as those who had not responded to an adequate dose and duration of treatment.
- Participants who were using medication for migraine prophylaxis and had not maintained a stable dose (i.e., no dose adjustment) for at least 30 days prior to screening.
- Participants who had received chronic opioid therapy (more than 3 consecutive days) within the 30 days prior to screening, those with active chronic pain syndromes (such as fibromyalgia, chronic pelvic pain, or complex regional pain syndrome), known allergy to any component of the test product.
- Participants who were suffering from medical or psychiatric conditions that could have increased the risk of adverse events or interfered with study assessments and those with history of drug or alcohol abuse within the last 3 months.
- Participants who had taken part in another investigational drug trial within the last 30 days, immune-compromised patients such as HIV Positive patients and those undergoing treatment with steroids or immunomodulators, seriously ill or mentally challenged individuals.

Sample size: Sample size was calculated using Sample Size Calculator Pro. Version 1.0. considering the hypothetical proportion before treatment as 90% and proportion after treatment as 20%. With alpha error 0.05 and beta error 0.2. The required minimum sample size was calculated to be 12 per treatment. 24 participants were enrolled in this study to increase the power of the study.

Study Procedure:

All the study participants who satisfied the study criteria were included in the study. The study protocol, CRFs, product related information and informed consent form (in English & Tamil) were submitted to the Human Ethics Committee for necessary approval. Ethics Committee approval was obtained before initiating the trial from the site. Only after obtaining proper informed consent from the study participants, the study commenced, complying with the study protocol. 24 participants with migraine headache disorders were enrolled in this study. Demographic data, including gender, age (years), body weight (kg), height (cm) in terms of BMI (kg/m^2), tobacco use and medical history were recorded for each participants. Every participant underwent a thorough general and systemic examination. The enrolled patients received New Amrutanjan Headache Faster Relaxation

Roll on twice or thrice daily topically for one day**.** The roll-on was applied in a thin layer to the painful area, including the temples, the region below and adjacent to the base of the skull extending to the base of the neck, and the area behind and between the ears, within two hours of headache onset. The duration of dosing was 24 hours. Participants were asked to visit clinical facility/institution for their follow up visits on day 2. For 24 hours prior to admission to the study site and throughout the study period, participants were not allowed to consume alcohol, other substances of abuse, or analgesics. Analgesics (Aceclofenac and Paracetamol) were permitted only as rescue medication for severe pain during the study period. If concomitant medication was required during the study period (specifically analgesics), all such administrations were documented in the relevant forms. Participants were monitored throughout the study. None of the participants reported any adverse reactions or clinically significant abnormality. All evaluations made by the clinical investigator until the follow up were normal and acceptable. Participants were regularly asked about their well-being throughout the course of the study.

Evaluation Criteria:

A. Primary Outcome Measures

❖ Time to onset of relief of pain [Time frame: 0-120 minutes post dose]
❖ Time to achieve complete relief of pain [Time frame: 0-120 minutes post dose]
❖ Reduction in pain score on numeric pain rating scale (VAS) [Time frame: 30 seconds, 1 minute, 2minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90minutes, 105 minutes, 120 minutes post dose]
❖ Assessment of pain relief by using McGill Pain questionnaire. [Time frame: 0-120 minutes; minutes post dose and end of 24 hours]
❖ Participant's overall satisfaction for pain relief on a 7- point Likert Satisfaction scale [Time Frame: on day 2 post dose]

For statistical analysis, ordinal conversion of pain levels were assigned as 0–no pain up to 10-severe pain.

B. Secondary Outcome Measures

❖ Other complications like nausea, vomiting, photophobia, and phonophobia were monitored
❖ Any adverse events during the study period were monitored

Statistical Analysis:

All statistical analyses were performed using IBM SPSS Software Version 23.0. Descriptive statistics were given for baseline characteristics such as age and gender, as well as safety data including adverse events, rescue medication use, and tolerability profiles. Efficacy outcomes, such as time to onset and complete relief of pain, were reported as mean ± SD. Changes in pain intensity over time, as measured by the Visual Analogue Scale (VAS), were analyzed using Repeated Measures ANOVA. Pre- and post-treatment comparisons of McGill Pain Questionnaire scores were assessed using Wilcoxon signed-rank tests based on data distribution. Categorical variables, including Likert satisfaction scores and adverse events, were presented as frequencies and percentages.

RESULTS:

Thirty participants (N = 30) were screened for this study, out of which 24 participants were enrolled and completed the study. Among the 24 participants, males were 9 (37.5%) and females were 15 (62.5%). The age of the participants ranged between 18 and 60 years, and majority of them fall under the category of 31-40 years. Fifty percentage of the participants fall under over-weight category [Table-1].

Table 1: Demographic details of the participants

Demographic data	**No.of participants (%)**
Gender	
Male	9 (37.5%)
Female	15 (62.5%)
Age (years)	
18-20	2 (8%)
21-30	1 (4%)
31-40	10 (42%)
41-50	7 (29%)
51-60	4 (17%)
BMI (kg/m^2)	
18.5 to 24.9 (Healthy weight)	5 (21%)
25 to 29.9 (Overweight)	12 (50%)
>30 (Obesity)	7 (29%)

Participants experienced the onset of pain relief rapidly, with an average onset time of 1 minute and 49 seconds after application of the product. The standard deviation of 22.08 seconds indicates that the onset was fairly consistent across participants, with most experiencing relief within 2 minutes. This highlights the quick-acting nature of the product. Among participants who achieved complete pain relief (n=10), the average time taken was approximately 22 minutes.

This suggests that for a subset of users, the product was not only fast-acting but also effective in eliminating pain completely within a relatively short duration. The mean duration of pain relief following application of the New Amrutanjan Headache Faster Relaxation Roll-On was 111 minutes and 15 seconds, with a standard deviation of 15 minutes and 33 seconds. This indicates that, on average, participants experienced sustained pain relief for nearly two hour. These findings suggest that the product provides consistent and prolonged therapeutic effects following application [Table-2].

Table 2: Onset of pain relief, complete pain relief and duration of action of New Amrutanjan Headache Faster Relaxation Roll On

Parameter	**Time (Mean ± SD)**
Time taken for onset of pain relief (n=24)	1 min 49 seconds ± 22.08 seconds
Time to achieve complete relief of pain (n=10)	22 min ± 13min 13seconds
Duration of action – Pain relief (n=24)	111 minutes15 seconds ± 15 minutes 33 seconds

Statistically significant reduction was observed in pain scores over time, with the greatest effect seen between 10–30 minutes post-application. Pain relief was sustained for up to 60–75 minutes before gradually returning. The results of the Repeated Measures ANOVA confirmed that the observed reduction in pain scores over time was statistically significant and attributable to the efficacy of New Amrutanjan Headache Faster Relaxation Roll On [Table-3].

Table 3: **Reduction in pain score on numeric pain rating scale (VAS)**

Time points	**N**	**Mean ± SD**
0 min (Baseline)	24	4.875±0.8502
30 seconds	24	4.875±0.8502
1 min	24	4.708±1.0826
2 min	24	3.583±0.9743

5 min	24	2.875±1.1156
10 min	24	2±1.1034
15 min	24	1.375±1.0959
30 min	24	1.042±1.0417
45 min	24	1.708±0.8065
60 min	24	2.25±0.8969
75 min	24	2.833±1.3077
90 min	24	3.167±1.2039
105 min	24	3.542±1.3181
120 min	24	3.625±1.279
P-value	**0.0001**	

p-value < 0.001 statistically significant.

The McGill Pain Questionnaire results confirm that New Amrutanjan Headache Faster Relaxation Roll On effectively reduced multiple dimensions of pain, not just intensity. The statistically significant improvement across all types of pain (e.g., shooting, stabbing, sharp, cramping) demonstrates broad-spectrum analgesic properties, supporting both subjective and objective outcomes [Table-4].

Table 4: **Pain Relief by McGill Pain Questionnaire**

Mc Gill Score	**Pre (0 minutes)**	**Post (120 minutes)**	**P-value**
	Mean ± SD	**Mean ± SD**	
Pain severity	1.957 ± 0.2085	1.217 ± 0.5997	**0.001**
Shooting type of pain	2 ± 0.5222	1.478 ± 0.8458	**0.0001**
Stabbing type of pain	1.87 ± 0.3444	1.435± 0.5898	**0.0001**
Sharp type of pain	2 ± 0	1.261 ± 0.6192	**0.0001**
Cramping type of pain	2 ± 0	1.25 ± 0.4629	**0.0001**

p-value < 0.01 statistically significant.

The participants' overall satisfaction scores indicated a positive perception of pain relief following product use. 71% of participants reported agreement or strong agreement (scores 5–7) with the effectiveness of the intervention, while 29% remained neutral [Table-5].

Table 5: Participant's Overall Satisfaction for Pain Relief on a 7- Point Likert Satisfaction Scale

Overall Pain Relief Score	**Frequency (n)**	**Percentage (%)**
4 – Neutral	7	29.2
5 - Somewhat Agree	8	33.3
6 – Agree	7	29.2
7 - Strongly Agree	2	8.3
Total	24	100

Scores: 1- Strongly Disagree, 2- Disagree, 3- Somewhat Disagree, 4- Neutral, 5- Somewhat Agree, 6-Agree, 7- Strongly Agree 41.7% participants did not require any rescue medication, indicating that the product was effective as a standalone therapy for a substantial proportion of users. Among those who did use additional analgesics, the majority opted for Paracetamol, a relatively mild pain reliever [Table-6].

Table 6: Concomitant Medications Used for Pain Relief (Rescue Medication)

Medications	**Frequency (n)**	**Percentage (%)**
Tab. Aceclofenac with Paracetamol FDC	4	16.6
Tab. Paracetamol 650 mg	10	41.7

No use of rescue medications	10	41.7
Total	24	100

DISCUSSION:

Migraine is a complex neurological disorder characterized by episodes of moderate-to-severe headaches. These episodes can significantly impact daily activities and the quality of life of individuals.[7] Though oral drugs are available to treat and prevent migraine attacks, topical therapy pose as a safety option for the patients. Hence, this study was done to analyze the safety, tolerability and efficacy of New Amrutanjan Headache Faster Relaxation Roll On in participants experiencing migraine headaches.

Among the 24 participants, ratio of male and female population were 67.5% and 32.5%. Our study shows female preponderance which is similar to the study done by Bhupendra et al with a female preponderance ratio of 16.4%and 8% respectively.[8]The higher prevalence in women is typically attributed to hormonal fluctuations especially estrogen.[9] Majority of the participants fall under the category 31 – 50 years of age. This finding is in accordance with the study done by Brett R et al.[10]

The product demonstrated a rapid onset of pain relief, with a mean time to onset of 1 minute and 49 seconds, suggesting that the formulation acts swiftly. Complete pain relief was observed in a subset of participants (n=10) at a mean of 22 ± 13.13 minutes, while the mean duration of pain relief lasted approximately 111 minutes, indicating a sustained action for nearly two hours. A systematic review on herbal treatment of migraine suggested that several herbal medicines present as potential options to improve the treatment of migraine.[11] Pain intensity, as assessed using the VAS (Visual Analogue Scale), showed a statistically significant reduction ($p = 0.0001$) from baseline up to 120 minutes, with the most pronounced relief seen within the first 30 minutes.

Further subjective assessments using the McGill Pain Questionnaire revealed significant improvements across various types of pain descriptors (shooting, stabbing, sharp, cramping), supporting the multidimensional analgesic effects of the product. The rapid and sustained pain relief can be attributed to the combination of Camphor, Menthol, and Methyl Salicylate. Menthol and camphor provide a cooling counter-irritant effect through TRPM8 receptor activation.[12] Methyl salicylate offers anti-inflammatory action through COX inhibition, mimicking aspirin-like effects. This multimodal mechanism is particularly beneficial in migraines, where pain is multifactorial (vascular, neurological, and inflammatory).

Moreover, the Likert satisfaction scores indicated moderate to high user satisfaction, with a majority of participants rating their experience between scores 4 and 7, and 41.7% not requiring any rescue medications, highlighting the stand alone effectiveness of the roll-on in a considerable proportion of users.

No complications such as nausea, vomiting, photophobia or phonophobia were reported during the study period suggesting that the product is well-tolerated. The absence of side effects is an essential advantage, especially when compared to oral pharmacological therapies that often carry systemic risks. The New Amrutanjan Headache Faster Relaxation Roll-On did not cause any skin sensitivity reactions and was found to be safe and well-tolerated when used in the prescribed dosage form.

CONCLUSION:

In conclusion, the findings from this interventional study support the New Amrutanjan Headache Faster Relaxation Roll On as a safe, well-tolerated, and effective topical option for the relief of migraine headaches. Its rapid onset of action, sustained pain relief, and favorable safety profile make it a promising non-pharmacological adjunct or alternative for migraine management. These results are encouraging and warrant larger-scale, controlled studies to validate these outcomes, explore long-term benefits, and compare its efficacy with standard oral therapies. For individuals seeking quick relief with minimal systemic side effects, this formulation presents a practical and accessible solution

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CONFLICTS OF INTEREST: None

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