

An observational study on usefulness of *Bromium 30C* in atopic respiratory complaints by assessing serum immunoglobulin E levels

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Abstract

Background: Atopic disorders represent a major health problem worldwide affecting 5%–30% of the population. The present study evaluates the action of *Bromium 30C* in reducing serum IgE levels. **Objective:** To assess the variation of serum IgE levels before, during and after intervention with *Bromium 30C*. **Materials and Methods:** Thirty cases of atopic respiratory complaints (diagnosed based on clinical history, CMDT guidelines and serum IgE values during the first visit) were selected as per the inclusion criteria using purposive sampling technique. *Bromium 30C* was prescribed for these cases and followed for 3 months. *Bromium 30C* was repeated twice daily for 2 weeks and placebos were administered in between. Serum IgE values were checked every month. The data was statistically analysed using mean, standard deviation and analysis of variants (ANOVA). **Results:** ANOVA for repeated measures showed $P = 0.000$, which is highly significant. Pairwise comparison of serum IgE levels in before and during, during and after treatment groups showed $P = 0.007$, which is highly significant. Pairwise comparison of serum IgE levels in during and after treatment group showed $P = 0.016$, which is significant. **Conclusion:** There is a significant reduction in serum IgE levels in cases of atopic respiratory complaints during and after homoeopathic treatment with *Bromium 30C*.

Keywords: Analysis of variants, Atopic respiratory complaints, *Bromium 30C*, Serum immunoglobulin E

INTRODUCTION

Atopic disorders represent a major health problem worldwide affecting 5%–30% of the population. Immediate or Type I hypersensitivity reaction, where production of immunoglobulin E (IgE) antibody causes various changes such as release of vasoactive amines and other mediators from mast cells, recruitment of inflammatory cells, etc., is well understood in the pathogenesis of atopic respiratory complaints.^[1] A randomised controlled trial done using the homoeopathic preparation *Galphimia glauca 6C* with placebo in hay fever/rhinitis cases demonstrated the efficacy of Homoeopathy using one indicated remedy and was defined as high quality by three meta-analyses of Homoeopathy.^[2-4]

Passalacqua *et al.* conducted a systematic review on complementary and alternative medicine for rhinitis and asthma, concluded that the evidence for a specific effect of Homoeopathy is weak.^[5] A pilot study done in India assessed the efficacy of homoeopathic remedies, chosen strictly on

individualisation and symptom similarity, in bringing changes in serum IgE level, absolute eosinophil count and allergic rhinitis symptom scores.^[6]

Reilly *et al.*^[7] studied homoeopathic treatments of hay fever and asthma in one hundred and fifty-eight patients. The responses were judged by using a visual analogue scale, which showed a significantly greater response to the homeopathic therapy and a corresponding reduction in the need for antihistamines in these patients.

There have been a few reviews of randomized, controlled trials published regarding the use of Homeopathy for asthma treatment. Six trials were included in a recent review.^[8,9]

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These trials were of variable quality and the results of the studies are conflicting in terms of effects on lung function. The authors underlined that standardized treatments in these trials are unlikely to represent common homeopathic practice where treatment tends to be individualized. There is a need for observational data to document the different methods of homeopathic prescribing and how patients respond.^[10]

Homoeopathic remedy *Bromium* has a marked effect on the respiratory system, especially the larynx and trachea.^[11] Many of the respiratory symptoms of *Bromium* bear a close resemblance to atopic respiratory symptomatology. Thus, this observational, cohort, single arm, interventional study was conducted to assess the variation of serum IgE values in cases of atopic respiratory complaints where *Bromium* 30C is prescribed. This study tries to integrate the knowledge of disease (atopic respiratory complaints), knowledge of medicine (*Bromium*) and application of this knowledge to confirm whether there exists any role for the remedy *Bromium* to alter the serum IgE values in atopic respiratory complaints. The present study becomes unique as the action of *Bromium* 30C alone is studied in relation with serum IgE levels.

Objective

To assess the variation of serum IgE levels before, during and after treatment in cases of atopic respiratory complaints where *Bromium* 30C is prescribed.

MATERIALS AND METHODS

Period of study

The study was conducted on the cases available from April 2014 to March 2016.

Sample size

The sample consisted of thirty cases of atopic respiratory complaints visiting the OPD, IPD and Peripheral Centres of Father Muller Homoeopathic Medical College, Mangalore during the specified period.

Type of study

This was a single-arm, quasi-experimental, interventional, prospective, before, during and after treatment comparison pilot study without control.

Inclusion criteria

- Both sexes aged between 18 and 50 years
- Cases of atopic respiratory complaints in which serum IgE levels are above 200 IU/ml^[12]
- Cases of atopic respiratory complaints where *Bromium* is indicated and prescribed the same in the 30th potency were included in the study.

Exclusion criteria

- Patients who were on homoeopathic medicines other than *Bromium* 30C
- Taking medicines from other systems for any other complaint.

Materials

Standardised case record

Serum IgE levels were assessed using Cobas - 6000 fully automated analyser.

Method

Thirty cases of atopic respiratory complaints were selected as per the inclusion criteria using purposive sampling technique. Diagnoses of the cases were made based on relevant clinical history, and serum IgE values obtained during the first visit according to CMDT guidelines.^[13] The 30 potency of *Bromium* was prescribed for the above cases and was followed for a period of 3 months.^[11] The data were presented in standardised case record (SCR).

Remedy used

The 30 potency of homoeopathic medicine *Bromium*, manufactured by Father Muller Homoeopathic Pharmaceutical Division (which prepares the drug according to Homoeopathic Pharmacopoeia of India), was used in the study. Three globules of *Bromium* 30C (number 40 size) were given twice daily for a period of 2 weeks and placebos were administered in between if needed. Follow-ups were watched and analysed as per criteria set up in each case according to standard guidelines of Homoeopathy using the symptomatology of the patient as mentioned below.

Follow up and Symptomatic assessment

Each follow up was of 2 weeks duration, and assessed according to the guidelines given in standardised case record follow-up sheet where each symptom of the patient pertaining to allergic respiratory complaint was graded according to the intensity, aggravation, amelioration, presence or absence. The major symptoms considered in cases of allergic rhinitis were coryza, sneezing, itching of nose and nose block, and in cases of atopic asthma were breathlessness, cough and wheezing with a strong history of atopy in both diagnoses.

An estimation of serum IgE value for each case was done in the beginning before starting homoeopathic treatment. Over a period of time, when a patient came for consecutive follow-ups, serum IgE values of each patient were estimated again, minimum twice, which was after 1 month and after 3 months of treatment. This provided an idea for comparing serum IgE values in atopic respiratory complaints before, during and after treatment, after prescribing *Bromium* 30C. The flow chart of study given as Figure 1.

Statistical analysis

The collected data were analysed by mean, standard deviation and analysis of variants (ANOVA).

Research hypothesis

There is a significant decrease in serum IgE values in atopic respiratory complaints during and after homoeopathic treatment with *Bromium* in the 30th potency.

Null hypothesis

There is no significant decrease in serum IgE values in atopic respiratory complaints during and after homoeopathic treatment with *Bromium* in the 30th potency

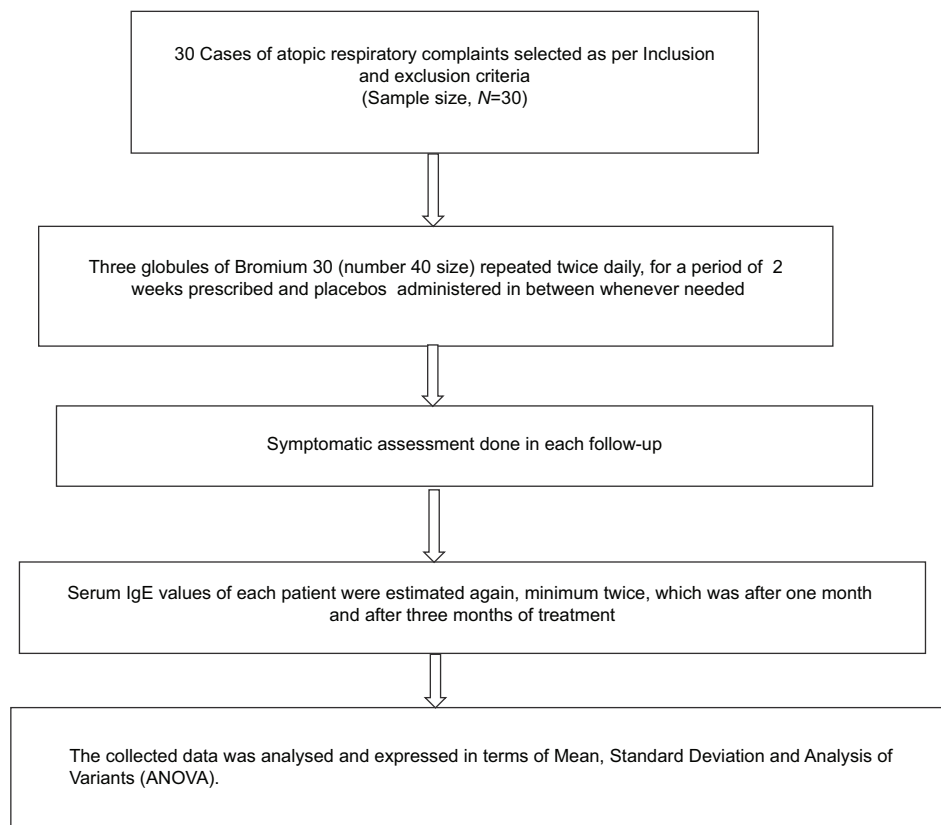


Figure 1: Flow chart of the study

RESULTS

This study of thirty patients showed a higher female prevalence (67%) with the 18-23 years’ age group being the most affected (33.33%) by atopic respiratory complaints. Allergic rhinitis constituted the maximum number of cases (80%) and atopic bronchial asthma constituted 20% of the cases [Table 1]. Thirty diagnosed cases of atopic respiratory complaints (allergic rhinitis and atopic bronchial asthma) were studied for a period of minimum 3 months. Serum IgE values were checked thrice, (before, during and after the treatment) with a minimum 1-month interval between each measurement. The following observations were made: mean serum IgE levels before, during and after treatment were 1067.39, 913.59 and 852.393 IU/ml, respectively. ANOVA for repeated measures shows $P = 0.000$, which denotes a highly significant reduction in mean serum IgE values before, during and after homoeopathic treatment with *Bromium 30C* in atopic respiratory complaints [Table 2].

Pairwise comparison of serum IgE levels in before and during treatment group shows a mean difference of 153.795, and $P = 0.007$ denotes that there is a highly significant reduction in serum IgE levels before and during treatment with *Bromium 30C*. Pairwise comparison of serum IgE levels in during and after treatment group shows a mean difference of 61.99, and $P = 0.016$ denotes that there is a significant reduction in serum IgE levels during and after treatment with

Table 1: Baseline characteristics

(A) Distribution of cases according to gender		
Gender	Frequency	Percentage
Male	10	33
Female	20	67
Total	30	100
(B) Distribution of cases according to age group		
Age group	Frequency	Percentage
18-23	10	33.33
24-29	6	20.00
30-36	5	16.66
37-42	5	16.66
43-50	4	13.30
Total	30	100.00
(C) Distribution of cases according to diagnosis		
Diagnosis	Frequency	Percentage
Atopic bronchial asthma	06	20
Allergic rhinitis	24	80
Total	30	100

Bromium 30C. Pairwise comparison of serum IgE levels in before and after treatment group shows a mean difference of 214.993, and $P = 0.007$ denotes that there is a highly significant reduction in serum IgE levels before and after treatment with *Bromium 30C* [Table 3].

Table 2: Mean serum immunoglobulin E levels before, during and after treatment

	N	Mean	Std Deviation	95% Confidence Interval for Mean		ANOVA F for repeated measures	P
				Lower Bound	Upper Bound		
				Before	30		
During	30	913.59	1039.545	525.42	1301.76		<0.001,
After	30	852.393	984.0642	484.938	1219.849		0.000

ANOVA: Analysis of variance; HS: Highly significant

Table 3: Pairwise comparisons – Serum immunoglobulin E levels before, during and after treatment

I	Factor 1	J	Mean difference (I–J)	SE	Change (%)	P
		After	214.993	48.401	20.14	0.000 (HS)
During		After	61.99	20.285	6.70	0.016 (S)

HS: Highly significant; S: Significant; SE: Standard error

DISCUSSION

It was observed that there was a highly significant reduction in serum IgE values in before and after, and before and during treatment groups. Significant reduction in serum IgE value was observed in during and after treatment group.

The strengths of this study are utilising the specific effect of Homoeopathy in allergic rhinitis and atopic asthma using *Bromium* 30C as the medicine and incorporating Serum IgE levels for the same. The weaknesses are small sample size ($n=30$), no control group selected to compare the results and no randomisation done.

One systematic review involving a single homoeopathic remedy (*G. glauca*) for treating allergic rhinitis had been published in English.^[14] Three out of four studies included in that review reported significant results in favour of the intervention; however, it only included one homoeopathic medicine. Two important drawbacks of this review were that of the included trials, neither used validated outcome measures nor intention-to-treat analyses. Apart from Ernst, no systematic review evaluating only homoeopathic treatment for allergic rhinitis had been published in English. This study provides scientific evidence in Homoeopathy by nullifying the main drawbacks of the above study using serum IgE values and by utilising intention to treat analysis.

Passalacqua *et al.*^[5] conducted a systematic review on complementary and alternative medicine for rhinitis and asthma, concluded that the evidence for a specific effect of Homoeopathy is weak. This study provides a strong evidence for specific effect of Homoeopathy in rhinitis and asthma using *Bromium* 30C as the medicine.

A single-arm, experimental, interventional, prospective, non-randomised, before and after comparison pilot study without control was carried on thirty participants suffering from allergic rhinitis in India.^[6] The trial was aimed to assess the efficacy of homoeopathic remedies, chosen strictly on individualisation and symptom similarity, in bringing changes in serum IgE level, absolute eosinophil count and allergic rhinitis symptom scores (approved by the Institutional Review Board) by comparing the score before medication (baseline) with score after medication. Outcome measures were assessed and analysed after 1 year. After 1 year of homoeopathic treatment, reduction in serum IgE level, absolute eosinophil count and symptom score were statistically highly significant.^[6]

This study assessed the action of a single remedy *Bromium* 30C (in contrast to various homoeopathic medicines in the above study) and assessed only variations in serum IgE levels before, during and after treatment. The other study assessed changes in absolute eosinophil count also apart from changes in serum IgE but did not include atopic bronchial asthma. Both of these studies followed a similar methodology to study atopic respiratory complaints, though varying parameters and outcome measures were used in the assessment. However, both studies are non-randomised pilot studies which involved only a small group of thirty patients.

A review article published in India comprised 10 selected publications of observational studies and drug oriented studies where Homoeopathic treatment was used for the management of asthma. This review concluded positive outcome in controlling acute episodes of asthma, reducing the frequency and intensity of subsequent episodes and weaning of bronchodilators and other allopathic drugs. But, Homoeopathic medicine *Bromium* was not prescribed in none of the 10 constituent studies mentioned under the review. The review also recommended further pragmatic trials including randomized control studies, as only observational studies had been conducted.^[15]

CONCLUSION

There is a significant reduction in serum IgE levels with symptomatic improvement in cases of atopic respiratory complaints during and after homoeopathic treatment with *Bromium* 30C.

Limitations

- The sample size is small ($n = 30$)
- No control group was included along with the study group to compare test results.

Recommendations

- A study on a larger scale with randomisation and double blinding could be undertaken
- Bigger sample with extended time of research would provide better results
- A quality of life questionnaire for atopic bronchial asthma could be added to the parameters used in this study.

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Conflicts of interest

None declared.

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इम्युनोग्लोबिन ई सीरम के स्तर के आकलन के द्वारा श्वास संबंधी समस्याओं में ब्रोमियम 30सी की प्रभावशीलता का एक अध्ययन

सार

पृष्ठभूमि: एटोपिक विकार दुनिया भर में एक बड़ी स्वास्थ्य समस्या है जो 5 प्रतिशत–30 प्रतिशत जनसंख्या को प्रभावित करते हैं। प्रस्तुत अध्ययन ब्रोमियम 30सी के सीरम आईजीई स्तरों को कम करने के प्रभावों का मूल्यांकन करता है।

उद्देश्य: एटोपिक श्वास संबंधी शिकायत के मामलों में जहां ब्रोमियम 30सी निर्धारित है वहां होम्योपैथिक उपचार के पहले, दौरान और बाद में सीरम आईजीई के स्तरों में परिवर्तन का मूल्यांकन।

सामग्रियां और विधियां: एटोपिक श्वास संबंधी शिकायतों के तीस मामले (नैदानिक इतिहास, सीएमडीटी दिशानिर्देश और पहले दौर के दौरान सीरम आईजीई वैल्यू के आधार पर पहचाने गए) सोद्देश्य नमूना चयन तकनीक का प्रयोग कर शामिल करने के मापदंडों के अनुसार चयनित किए गए। इन मामलों के लिए ब्रोमियम 30सी दी गई और तीन महीनों के लिए जारी रखी गई।

दो सप्ताह के लिए दिन में दो बार ब्रोमियम 30सी दी गई और बीच-बीच में प्लासिबो दी गई। प्रत्येक माह सीरम आईजीई वैल्यू जांची गई। औसत, मानक विचलन और प्रकारों के विश्लेषण (अनोवा) के प्रयोग से परिकल्पना को सांख्यिकीय रूप से विश्लेषित किया गया।

परिणाम: दोहरे उपायों के लिए अनोवा ने पी=0.000 प्रदर्शित किया जोकि अत्यधिक महत्वपूर्ण है। पहले और बीच में, बीच में और बाद के उपचार समूहों में सीरम आईजीई स्तरों की आपस में तुलना ने पी=0.007 प्रदर्शित किया जोकि अत्यधिक महत्वपूर्ण है। बीच में और बाद में के उपचार समूहों में सीरम आईजीई स्तरों की आपस में तुलना ने पी=0.016 प्रदर्शित किया, जो कि महत्वपूर्ण है।

निष्कर्ष: एटोपिक श्वास संबंधी शिकायतों के मामलों में ब्रोमियम 30सी से होम्योपैथिक उपचार के दौरान और बाद में सीरम आईजीई स्तरों में महत्वपूर्ण कमी आई।

Eine Studie zur Wirksamkeit von *Bromium C 30* bei atopischen Atemwegserkrankungen durch die Beurteilung des Serum-Immunglobulin-E-Spiegels

Abstrakt

Hintergrund: Atopische Störungen stellen weltweit ein großes Gesundheitsproblem dar, das 5%–30% der Bevölkerung betrifft. Diese Studie wurde durch drei Metaanalysen von hoher Qualität eingestuft. Die vorliegende Studie untersucht die Wirkung von *Bromium C 30* hinsichtlich der Reduktion des Serum-IgE-Spiegels.

Ziel: Beurteilung der Schwankungen der Serum-IgE-Werte vor, während und nach der homöopathischen Behandlung bei atopischen Atemwegserkrankungen, bei denen *Bromium C 30* verschrieben worden ist.

Materialien und Methoden: 30 Fälle von atopischen Atemwegserkrankungen (diagnostiziert auf der Grundlage der klinischen Geschichte, CMDT-Richtlinien und Serum-IgE-Werte während der ersten Visite) wurden nach den Einschlusskriterien unter Verwendung einer zweckmäßigen Probenahmetechnik ausgewählt. In diesen Fällen wurde *Bromium C 30* verschrieben und für drei Monate nachbeobachtet. *Bromium C 30* wurde zweimal täglich zwei Wochen lang wiederholt, und Placebos wurden dazwischen verabreicht. Serum-IgE-Werte wurden monatlich überprüft. Die Hypothese wurde statistisch unter Verwendung von Mittelwert, Standardabweichung und Analyse von Varianten (ANOVA) analysiert.

Ergebnisse: ANOVA bei wiederholte Maßnahmen zeigte $P = 0,000$, was sehr signifikant ist. Der paarweise Vergleich der Serum-IgE-Spiegel vor und während, während und nach Behandlungsgruppen zeigte $P = 0,007$, was hoch signifikant ist; ebenso wie der paarweise Vergleich der Serum-IgE-Spiegel während und nach der Behandlungsgruppe, der $P = 0,016$ ergab, was signifikant ist.

Fazit: Es gibt eine signifikante Reduktion des Serum-IgE-Spiegels bei atopischen Atemwegserkrankungen während und nach der homöopathischen Behandlung mit *Bromium C 30*.

Estudio sobre la efectividad de *Bromium 30C* en afecciones respiratorias atópicas, evaluada a través de los niveles de la inmunoglobulina E sérica

Resumen

Fundamento: Los trastornos atópicos representan un problema de salud mundial que afecta al 5%–30% de la población. Este estudio ha sido referenciado en tres metaanálisis de homeopatía como de alta calidad. En el presente estudio, se evalúa la acción de *Bromium 30C* en la reducción de los niveles séricos de la IgE.

Objetivos: Evaluación de las variaciones de los niveles séricos de la IgE antes, durante y después del tratamiento homeopático en casos de alteraciones respiratorias atópicas, en los que se prescribió *Bromium 30C*.

Materiales y métodos: Se seleccionaron 30 casos con alteraciones respiratorias atópicas (con diagnóstico basado en la historia clínica, en las directrices CMDT [*CURRENT Medical Diagnosis and Treatment*] y los niveles séricos de IgE durante la primera visita) según criterios de inclusión utilizando la técnica de muestreo deliberado. *Bromium 30C* se repitió dos veces al día durante 2 semanas y entre medio se administraron placebos. Cada mes se comprobaron los niveles séricos de IgE. La hipótesis se analizó estadísticamente utilizando la media, la desviación típica y el análisis de varianza (ANOVA).

Resultados: El análisis ANOVA de medidas repetitivas mostró una $P = 0,000$, lo cual significa una elevada significación. La comparación pareada de los niveles séricos de IgE en el grupo antes y durante el tratamiento, así como en el grupo durante y después del tratamiento, se constató una $P = 0,007$, la cual posee una elevada significación. La comparación pareada de los niveles séricos de IgE en el grupo durante y después del tratamiento mostró una $P = 0,016$, la cual es significativa.

Conclusiones: En los casos de alteraciones respiratorias atópicas se produjo una reducción significativa de los niveles séricos de IgE durante y después del tratamiento homeopático con *Bromium 30C*.

Une étude sur l'efficacité de *Bromium* 30 dans les cas de troubles respiratoires atopiques en évaluant les taux d'immunoglobulines E sériques

Résumé

Contexte: Les troubles atopiques représentent un problème de santé majeur à travers le monde entier touchant 5 à 30 % de la population. L'étude actuelle évalue l'action de *Bromium* 30 dans la réduction des taux d'IgE sériques.

Objectif: Évaluer la variation des taux d'IgE sériques avant, pendant et après le traitement homéopathique dans les cas de troubles respiratoires atopiques où le *Bromium* 30 est prescrit.

Matériels et Méthodes: Trente cas de troubles respiratoires atopiques (diagnostiqués selon les antécédents cliniques, les directives de CMDT et les valeurs d'IgE sériques lors de la première visite) ont été sélectionnés selon les critères d'inclusion à base de la technique d'échantillonnage par choix raisonné. Il a été répété deux fois par jour pendant 2 semaines et des placebos ont été administrés de temps en temps. Les valeurs d'IgE sériques ont été contrôlées chaque mois. L'hypothèse a été analysée statistiquement par l'écart moyen, l'écart-type et l'analyse de la variance (ANOVA).

Résultats: L'ANOVA pour les mesures répétées a montré que $P = 0,000$, ce qui est très significatif. La comparaison par paire des taux d'IgE sériques chez les groupes avant et pendant le traitement, et pendant et après le traitement a montré que $P = 0,007$, ce qui est très significatif. La comparaison par paire des taux d'IgE sériques chez les groupes pendant et après le traitement a montré que $P = 0,016$, ce qui est significatif.

Conclusion: Il y a une réduction significative des taux d'IgE sériques dans les cas de troubles respiratoires atopiques pendant et après le traitement homéopathique avec *Bromium* 30.

透過免疫球蛋白E血清水平評估溴30C用於異位性呼吸道疾病的功效研究

摘要

背景: 異位性疾病是影響全球5%~30%人口的主要健康問題。此研究為評估溴30C對降低免疫球蛋白E血清水平的作用。

目的: 評估異位性呼吸道疾病個案在處方溴30C治療之前、期間和之後免疫球蛋白E血清水平的變化。

材料及方法: 使用立意取樣方法按納入標準挑選了30個異位性呼吸道疾病個案（診斷根據臨床病歷、CMDT指引和第一次會診期間的免疫球蛋白E血清數值）。以上個案每日重複溴30C兩次，持續兩星期，並在之間給予安慰劑。每月檢查免疫球蛋白E血清數值。以平均值、標準差和變異數分析（ANOVA）作數據上的分析以證明是次研究的假設。

結果: 重複測量變異數分析顯示 $P = 0.000$ ，表示效果非常顯著。免疫球蛋白E血清水平的配對比較，治療組別在之前和期間、以及期間和之後的比較為 $P = 0.007$ ，顯示效果非常顯著。免疫球蛋白E血清水平在治療期間和之後的配對比較為 $P = 0.016$ ，表示效果顯著。

結論: 異位性呼吸道疾病個案使用順勢療法療劑溴30C期間和之後，免疫球蛋白E血清水平顯著降低。