



**KEY WORDS**

**helminths, intestinal parasites, immune system, gut-brain axis**

# Prophylaxis and natural treatment of Helminth infestation. Observational study on the action and efficacy of **Gunaelmint** and **Guna-Tanacetum** in intestinal parasite infections

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## ABSTRACT

Helminthiasis are intestinal diseases caused by parasites (helminths) and represent an important mortality risk in many countries characterized by poor hygienic-sanitary conditions. The intestinal parasitic infections are also frequent in most developed countries and especially affect children, with an incidence of 20%. Parasitic infestations alter the homeostasis of the cerebral-intestinal axis and present symptoms like insomnia, restlessness, abnormal appetite, malabsorption phenomena of nutrients and significant reduction of blood levels of some minerals. From an immunological point of view helminthiasis lead to increased host susceptibility against re-infestation and additional opportunistic infections. The clinical observational study GUNAELMINT is focused on helminthiasis related particularly to infestation with pinworms and aims to evaluate the effectiveness of the experimental treatment of helminthiasis with the dietary supplement Gunaelmint and homeopathic medicine Guna-Tanacetum. The study was conducted on 23 subjects enrolled and treated according to defined criteria with orally administered Gunaelmint and Guna-Tanacetum with symptomatic evaluation of parameters and safety through the monitoring of adverse events. Gunaelmint was administered for 1 week at the dose of 3 sachets/day followed by two weeks of wash-out and by a further week of treatment. Guna-Tanacetum was administered at a dose of 10 drops/3 times a day for 25 days (half-dose if under 6 years). Collected data show that the use of the food supplement Gunaelmint associated with Guna-Tanacetum can be proposed as an effective therapeutic option for helminthiasis and as prophylactic therapy in conditions of increased risk of infestation by helminths, especially in communities.

## INTRODUCTION

### Intestinal parasitic infestation

Helminthiasis are intestinal infestations caused by metazoan parasites (helminths) and represent an important cause of mortality and morbidity in many countries of the world, especially those where sanitation and hygiene are poor.<sup>1-2</sup>

Even in the most developed countries the intestinal parasitic infections are frequent and affect the whole population, especially children (incidence in the child population: 20%);<sup>3-4</sup> the Oxiuridae Family, in particular *Enterobius vermicularis*, appears to be the main responsible for helminth infestation in temperate zones, including Italy.<sup>4</sup>

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The infestation in children is usually due to contacts with the ground or with objects infested by parasites or their eggs; the oral ingestion of parasites starts the cycle of infestation. Helminths reach the adult stage in the lower gastrointestinal tract after about 2-6 weeks. Afterwards, usually during the night, the females migrate to the perianal area and lay their eggs inside the skinfolds. Afterwards, through a contact with fingers, the eggs move from the anal area to different objects (clothes, toys, etc.). Then, through contact or inhalation, the eggs infest a new subject or re-infest the infested child, thereby starting a new infestation cycle.<sup>1-4</sup>

The most common symptom of helminth infestation is **perianal itching** associated with perianal excoriation, resulting from continuous scratching, whereas other symptoms often associated with the presence of parasites are **abdominal pain, insomnia, irritability** and **restlessness**, or symptoms similar to **urticaria, asthenia, and appetite changes**.

Severe helminthiasis resulted in the migration of parasites to other organs (liver and lungs), inflammation of the colorectal area, vaginitis, inflammation of the cecum similar to appendicitis, formation of intraperitoneal granulomas and alterations in female fertility.<sup>3-5,9</sup>

Parasite infections have important effects on the homeostasis of the gut-brain axis (Gut-Brain Axis – GBA), a continuous feedback system between intestinal sensory neurons and motor neurons on the central nervous system level (CNS):<sup>10</sup> the presence of parasitic infestation induces a reduced expression of serotonin receptors (5-HT).<sup>11</sup> Serotonin is a key neurotransmitter in the cross-talk between the intestine and the CNS. The unbalance induced by a reduced response to the circulating 5-HT is the basis for the onset of symptoms such as insomnia, restlessness and appetite changes.

The alteration of the intestinal homeostasis caused by parasitic infestation can lead to malabsorption of nutrients resulting in weight loss (up to 10 kg in 40 days);<sup>12</sup> a significant reduction of certain minerals such as iron, magnesium and zinc was found in the blood of children suffering from helminth infestation, especially if the parasite is *Enterobius vermicularis*) and was related to malabsorption.<sup>13-15</sup>

Helminthiasis often leads to a balance of the immune response (especially Th2-mediated) so as to ensure the stability of the parasite-host combination. The immunocompetence of the host is directly down-modulated by the parasite in order to ensure its silent survival even for some years. This compensation mechanism, however, leads the host to an increased possibility to be re-infested or to be affected by further opportunistic infections.<sup>15</sup>

### **Treatment of helminth infestation: the GUNAELMINT study**

In developed countries the parasitic infestation is rarely symptomatic and apparently not harmful, therefore, a drug treatment is not considered necessary. Indeed; a treatment is required to the family doctor because of the "psychological disturbance" caused by the concept of "parasitic infestation." The conventional pharmacological therapy is based on the administration of mebendazole (or other molecules of the same class), usually 200 mg /day per os, regardless of the age of the patient.<sup>16-17</sup> The intake of mebendazole does not generally involve serious side effects because of its poor bioavailability. Nevertheless, the appearance of gastrointestinal disorders is associated with its prolonged intake (especially required in the event of re-infestation). Due to its teratogenicity, mebendazole cannot be administered during pregnancy and breastfeeding; the simultaneous presence in a family of children affected by helminth infestation and pregnant women (especially during the first three months) is difficult to manage from a therapeutic viewpoint.<sup>18</sup>

This is the therapeutic framework of the GUNAELMINT observational clinical study, aiming at the evaluation of the action of the food supplement Gunaelmint (Guna S.p.a. Milan, Italy) combined with Guna-Tanacetum (Guna S.p.a. Milan, Italy) in the treatment of helminth infestation, especially focusing on the compliance and safety of the two products. Gunaelmint is a food supplement containing extracts of pumpkin seeds (*Cucurbita pepo* L.), myrrh (*Commiphora myrrha* Eng.) and turmeric (*Curcuma longa* L.), that actively act on the detoxification of

the intestine and protect the liver and the kidneys. They create an environment that is unfavorable to helminths and help to eradicate them naturally. Guna-Tanacetum is a homeopathic medicine indicated for the treatment of nerve irritation and gastrointestinal disorders caused by intestinal parasites.

## MATERIALS AND METHODS

The GUNAELMINT study is an observational study with the aim of assessing the action of the food supplement Gunaelmint + Guna-Tanacetum in the treatment of helminth infestation.

Observational study on Gunaelmint + Guna-Tanacetum DIARY FOR PARENTS			
INITIALS OF THE CHILD'S NAME			
DATE OF BIRTH:			
TELEPHONE NUMBER:			
Suspected helminth infestation since:			
<b>SYMPTOM TREND:</b>			
<i>Please indicate the degree of severity of symptoms associated to helminth infestation: 10 = severe, unbearable symptom – 0 = no symptoms</i>			
SYMPTOM	BEFORE TREATMENT	6 DAYS AFTER TREATMENT START	26 DAYS AFTER TREATMENT START
Anal itching			
Restlessness and irritability			
Fatigue			
Insomnia			
Abdominal symptoms			
Urticaria and/or itchy skin			
Appetite alteration			
<b>Product compliance by the patient:</b>		POOR	
		SUFFICIENT	
		EXCELLENT	
<b>Adverse events:</b>		YES	NO
If yes, which:			
I authorize the processing of personal data as per D.L. 196 of 2003			
Parent's signature .....			

*Table 1:*

*Outline of the parents' diary prepared within the GUNAELMINT study.*

### Study design

The GUNAELMINT observational clinical study was conducted in Pediatrics practices (ASL-8 Arezzo; ASL-2 Milan) and private practices; 23 subjects were identified and enrolled, mostly children, according to the discretionary opinion of their pediatrician. The subjects enrolled in the study group were only those whose parents signed the relevant written informed consent (or just after direct acceptance and signature of the consent for subjects over 18 years of age). The total duration of the study was approximately 5 months, from February 2013 till June 2013 (4 months of enrollment and 26 days of treatment). A first screening was performed (T0) in order to select the patient according to the inclusion and exclusion criteria required by the protocol. Then, all the subjects enrolled underwent a second medical examination (T2) at the end of treatment in order to evaluate the aims.

The parents of the participants (or the subjects themselves) reported the severity and frequency (decimal scale: 10 = severe, unbearable symptom - 0 = no symptoms) of the following symptoms on a special parent's diary (*Table 1*): **anal itching, abdominal pain, insomnia, irritability and restlessness, fatigue, appetite changes, urticaria**. The data reported on the diaries were useful to evaluate the frequency and severity of the symptoms at T0, at T1 after 6 days of treatment, and at T2 after 26 days of treatment. The doctor who performed the study followed the enrolled subjects during the whole period of administration in order to assess the product safety through the monitoring of possible adverse events (AE).

### Treatments

- Composition of the food supplement Gunaelmint (one single sachet): pumpkin (*Cucurbita pepo* L.) seeds, 100 mg dry extract, aroma, myrrh (*Commiphora myrrha* Eng.) rubber resin dry extract 70 mg, turmeric (*Curcuma longa* L.) rhizome dry extract 33.3 mg, maltodextrin, thickeners: acacia gum, xanthan gum, acidity regulator: citric acid, sweetener: sucralose.
- Composition of Guna-Tanacetum: *Tanacetum vulgare* D1, *Artemisia vulgaris* D2, *Absinthium* D4; *Serpyllum* D3, *Chenopodium* D6. Ethanol 60%. The subjects enrolled in the study took the products according to the following regimen:
  - Gunaelmint: 1 week of treatment with 3 sachets/day per os followed by a two-week wash-out and by one further week of treatment with the same regimen.
  - Guna-Tanacetum: 10 drops/3 times daily for 25 days (half a dose if under 6 years of age):

## RESULTS

### Analysis of the primary endpoint

#### Anal Itching

The primary endpoint of this study was the evaluation of the anal itching, the most significant and characteristic symptom of the infestation caused by Pinworms (and helminth infestation in general).

At the end of treatment with Gunaelmint and Guna-Tanacetum, the anal itching, caused by laying the eggs of parasites in the skinfolds, appears to be significantly reduced: the  $\Delta T0-T2$  is -88.35% with recorded average scores **T0** = 6.35, SD  $\pm$  2.82; **T1** = 2.74, SD  $\pm$  2.26; **T2** = 0.74, SD  $\pm$  1.74. The statistical analysis of the data with Friedman test showed a significance equal to  $p < 0.00001$  (*Table 2*). The value recorded at **T1** and its significance (**T0 vs T1**:  $p < 0.00001$ ) show an efficient and quick action against the infestation since the very first 6 days of treatment.

### Analysis of the secondary endpoints

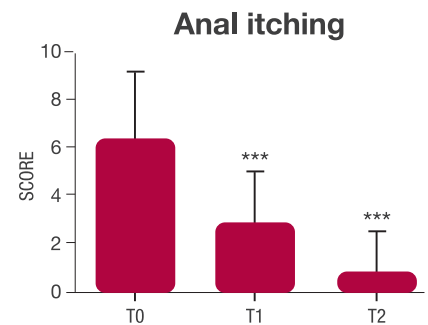
All the secondary endpoints were reached by taking Gunaelmint and Guna-Tanacetum; the intermediate scores recorded at T1 emphasize the rapid effects and the efficacy of the product action since the first six days of treatment for all parameters.

#### Abdominal Pain

Abdominal pain associated to helminth infestation was significantly reduced between the baseline T0 and the last T2 evaluation (Friedman test:  $p < 0.00001$ ). The episodes showed an average reduction of -87.83% (**T0**= 7.48,SD  $\pm$  2.31; **T1**= 4.00, SD} 2.43; **T2** = 0.91, SD  $\pm$  1.97) after treatment with Gunaelmint and Guna-Tanacetum (*Table 3A*).

#### Insomnia

Insomnia is a symptom associated with the reduction of the expression for serotonin receptors caused by parasitic infestation. The episodes of insomnia were significantly reduced between the baseline T0 and the last T2 evaluation, average value



*Table 2*

Graphical representation of the analysis of the primary endpoint. The reduction of anal itching is significant ( $\Delta T0-T2 = -88.35\%$ ).

-65.06%. (Friedman test:  $p < 0.00001$ ). The episodes showed a reduction ( $T_0 = 5.61$ ,  $SD \pm 3.54$ ;  $T_1 = 3.00$ ,  $SD \pm 2.49$ ;  $T_2 = 1.56$ ,  $SD \pm 2.49$ ) after treatment with Gunaelmint + Guna-Tanacetum (Table 3B).

#### Irritability and restlessness

Irritability and restlessness are also emotional states related to the reduction of the expression of serotonin receptors caused by parasitic infestation. Both parameters appeared to be significantly reduced between the baseline  $T_0$  and the last  $T_2$  evaluation (Friedman test:  $p < 0.00001$ ). The episodes showed an average reduction of -76.07% ( $T_0 = 6.52$ ,  $SD \pm 2.87$ ;  $T_1 = 3.74$ ,  $SD \pm 2.10$ ;  $T_2 = 1.56$ ,  $SD \pm 1.37$ ) after treatment with Gunaelmint and Guna-Tanacetum (Table 3C).

#### Fatigue

The increased susceptibility to fatigue appeared to be significantly reduced between the baseline  $T_0$  and the last  $T_2$  evaluation (Friedman test:  $p < 0.00001$ ). The episodes showed an average reduction of -61.51% ( $T_0 = 5.43$ ,  $SD \pm 1.23$ ;  $T_1 = 3.52$ ,  $SD \pm 1.97$ ;  $T_2 = 2.09$ ,  $SD \pm 1.78$ ) after treatment with Gunaelmint + Guna-Tanacetum (Table 3D).

#### Appetite alteration

Appetite alteration is a particularly sensitive parameter for its physiological and psychological importance.

The ability to eat properly is fundamental for a general wellbeing. After treatment with Gunaelmint and Guna-Tanacetum, the episodes of alteration showed an average reduction of -64.45% with the following partial scores:  $T_0 = 5.26$ ,  $SD \pm 2.78$ ;  $T_1 = 3.52$ ,  $SD \pm 1.57$ ;  $T_2 = 1.87$ ,  $SD \pm 1.79$  (test of Friedman:  $p < 0.00001$ ) (Table 3E).

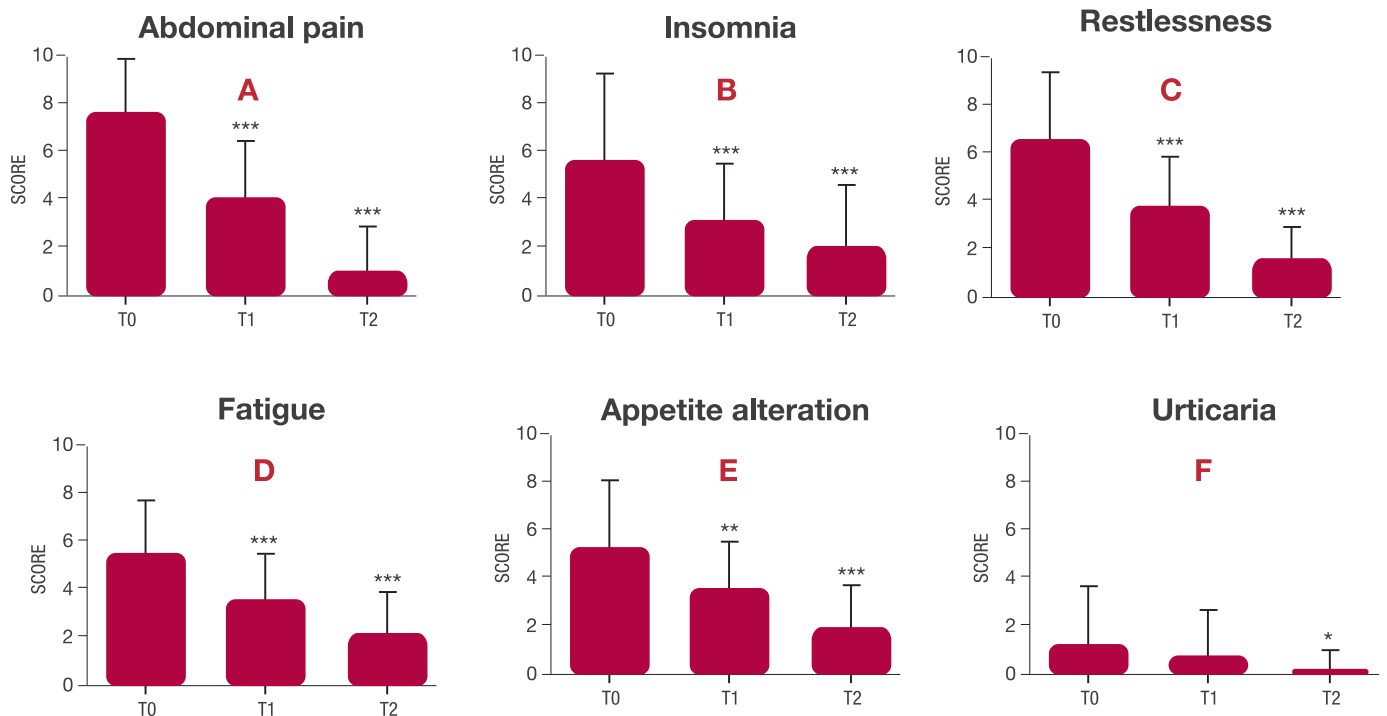
#### Urticaria

The episodes of urticaria appear to be significantly reduced between the baseline  $T_0$  and  $T_2$  and the last  $T_2$  evaluation (Friedman test:  $p = 0.039$ ). The score change indicates an average reduction of -86.05% ( $T_0 = 1.22$ ,  $SD \pm 2.45$ ;  $T_1 = 0.75$ ,  $SD \pm 1.91$ ;  $T_2 = 0.17$ ,  $SD \pm 0.83$ ) after treatment with Gunaelmint and Guna-Tanacetum. Between the  $T_0$  evaluation vs  $T_1$  and  $T_1$  vs  $T_2$  there is no significance, while between  $T_0$  and  $T_2$  a moderate "p" value here above was recorded. Due to a low frequency of urticaria episodes within the population of the study, this datum is of little importance concerning the action of Gunaelmint and Guna-Tanacetum (Table 3F).

Table 3

Secondary endpoints. All secondary endpoints were reached:

- (A) Abdominal pain  $\Delta T_0-T_2 = -87.83\%$ ;
- (B) insomnia  $\Delta T_0-T_2 = -65.06\%$ ;
- (C) irritability-restlessness  $\Delta T_0-T_2 = -76.07\%$ ;
- (D) fatigue  $\Delta T_0-T_2 = -61.51\%$ ;
- (E) appetite alteration  $\Delta T_0-T_2 = -64.45\%$ ;
- (F) urticaria  $\Delta T_0-T_2 = -86.05\%$ .



## Adverse event reporting and treatment safety

For the entire duration of the treatment no adverse events reported by the subjects enrolled were recorded by the doctors who carried out the study. Therefore, it is possible to confirm the safety of the products and of their use in accordance with the protocol.

## Discussion

The GUNAELMINT clinical study is an observational study which aims at evaluating the action of the food supplement Gunaelmint combined with the homeopathic medicine Guna-Tanacetum in the treatment of helminthiasis. The results obtained within the GUNAELMINT study showed that the use of Gunaelmint in association with Guna-Tanacetum is efficient in the treatment of symptoms due to helminth infestation. All the evaluated parameters showed a significant improvement confirming the effectiveness of the treatment. The primary endpoint, i.e., the reduction of the anal itching, was fully achieved, thus highlighting a decreased severity equal to **-88.35%**.

The evaluation of the secondary endpoints confirmed the positive trend registered by the primary outcome: all parameters showed average reductions varying from **-61.51%** (fatigue) and **-87.83%** (abdominal pain). The statistical analysis showed how a significant reduction in symptoms due to helminth infestation occurred since the very first six days of treatment, thus indicating that a rapid action is an important aspect of the treatment with Gunaelmint and Guna-Tanacetum.

A fundamental characteristic of the proposed treatment is the completeness of action of the active ingredients, able to act on all the aspects of the infestation: they contribute to the formation of an environment that is unfavorable to the onset of parasites, they are toxic to parasites themselves, they stimulate the immune system so as to contribute to a natural helminthes eradication. Moreover, they reduce the possibility of relapses and opportunistic infections, thus restoring the intestinal homeostasis, and reducing inflammation and malabsorption.

Gunaelmint active ingredients are dry extracts of pumpkin seeds (*Cucurbita pepo* L.), myrrh (*Commiphora myrrha* Eng.) and turmeric (*Curcuma longa* L.). The pumpkin seeds contain cucurbitina, a substance that creates unfavorable environmental conditions in the gut against the onset and survival of parasites.<sup>19</sup>

The extract of myrrh has a broad spectrum of action: it contributes to the formation of an environment that is hostile to helminths, stimulates the immune system down-regulated by parasites and exerts an anti-inflammatory and analgesic action, useful to reduce painful symptoms induced by parasite infestation.<sup>20-21</sup>

The extract of *Curcuma longa* is rich in curcuminoids, molecules that favor the natural helminthes eradication, acting as antioxidants and exerting an hepatoprotective function which is particularly important in the event of parasitic migration.<sup>23-24</sup>

Guna-Tanacetum is a hydroalcoholic solution containing *Tanacetum vulgare*, which is an effective anti-dysenteric that also exerts a soothing action on nervousness typical of helminth infestation. *Artemisia vulgaris* and *Absinthium*, are remedies also indicated for gastrointestinal disorders of nervous origin.

## Conclusions

The data collected within the GUNAELMINT observational study showed that the use of the food supplement Gunaelmint, in association with Guna-Tanacetum, ensures an effective action against helminths thanks to the synergistic action of its ingredients (broad spectrum of action), to the rapidity of action and to the capacity of maintaining this action over time.

The direct action on parasites, the indirect influence on the intestinal microenvironment and the support to the Immune System of the host are the key factors for the achievement of **quick, efficient and safe results, with high compliance for the patient.**

Furthermore, a therapeutic overlapping between Gunaelmint plus Guna-Tanacetum and a conventional drug treatment against helminth infestation (mebendazole or pyrantel pamoate) is possible in some cases and particularly

interesting. Depending on the various cases, Gunaelmint and Guna-Tanacetum can be administered (as per the regimen indicated) during a conventional treatment cycle and/or at the end of it to prevent any possible re-infestation. The use of Gunaelmint and Guna-Tanacetum is toxic to parasites but not to humans. This aspect, combined with the safety of the two products and their use, makes it a valid therapeutic option in certain conditions such as pregnancy or the presence of recurrent infestations, thus allowing to overcome the limitations and the side effects of conventional drug treatments.

The use of the food supplement Gunaelmint in association with Guna-Tanacetum can be proposed as prophylactic treatment in the event of increased risk of helminth infestation, especially within a community.

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