

# PROSPECTIVE OBSERVATIONAL STUDY ON INFANTS AND CHILDREN WITH ACUTE DIARRHOEA TREATED WITH GELATIN TANNATE®

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## RATIONALE AND OBJECTIVES

The main treatment for acute diarrhoea is oral rehydration to replace fluid and electrolytes.

Gelatin Tannate is a safe and effective treatment, supplementary to rehydration in children and infants.

The **primary objective of this study** is to observe how the acute diarrhoea has progressed at 12 h in children and infants treated with Gelatin Tannate according to clinical practice.

## METHODS

Multicentre, prospective, observational study. The information for the study was gathered in Health Centres in Almería. The maximum patient inclusion time was 4 months (between March and June, 2006).

•**Primary endpoints of the study:** Number and characteristics of bowel movements, patient weight, presence of vomiting and presence of fever. The criteria for effectiveness in this analysis is improvement of the diarrhoea and associated symptoms at 12 hours.

•**Patient selection:**

*Inclusion criteria:* Three or more watery stools a day with onset within previous 72 hours.

*Exclusion criteria:* Patients with chronic diarrhoea, immunosuppression, weight 20% or more below standard, systemic disease or the taking of anti-diarrhoea agents and/or antibiotics prior to inclusion.

•**Statistical tests:** The McNemar and Wilcoxon non-parametric tests were used for the statistical analysis. The T-test for paired data was used in the parametric bivariate contrasts.

## RESULTS

Data were obtained on a total of 125 children and infants. 97 patients met the inclusion criteria and none of the exclusion criteria and were considered for the statistical analysis.

•**Descriptive and comparative analysis of the population**

The gender distribution was 59.8% male and 40.2% female (N=82) with an average age of 2 years and a half (DE=2.02, Median=1.78). Acute diarrhoea was the main problem in 46.4% of patients (N=45) and presenting to the emergency in a 95.6% of cases (N=43). More than a third studied population presented an ECOG=1 (36.1%, N=35).

Table 1 shows the primary endpoints of the study at baseline and at 12 h. Figures 1-5 illustrate the main differences found.

TABLE 1	Baseline % (N total)	12 hours % (N total)	p-value
Number of bowel movements (≥4 bowel movements)	98.9 % (93)	7.9 % (63)	p<0,0005
Characteristics of the stools	(95)	(60)	N.A.
Watery	97,9 %	28,3 %	
Soft	1,1 %	56,7 %	
Normal	1,1 %	15 %	
Vomiting	72.6 % (95)	35 % (60)	p<0,0005
Dehydration	12 % (92)	4,5 % (44)	p=1,000
Bloody diarrhoea	8,4 % (95)	3,3 % (61)	p=1,000
No signs of peritonitis/sepsis	100 % (94)	100 % (43)	N.A.
	Mean ± SD (N total)	Mean ± SD (N total)	p-value
Temperature (°C)	37,8 ± 0,99 (94)	36,7 ± 0,51 (61)	p<0,0005
Weight (kg)	14 ± 7,9 (96)	14,3 ± 7,2 (17)	p=0,008

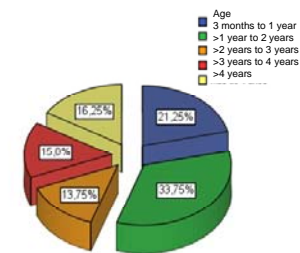


FIG. 1. DISTRIBUTION OF THE POPULATION BY AGE

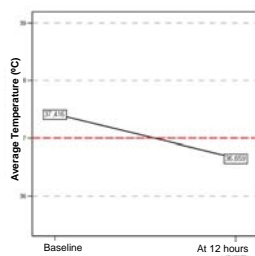


FIG. 2. TEMPERATURE: BASELINE vs 12 H

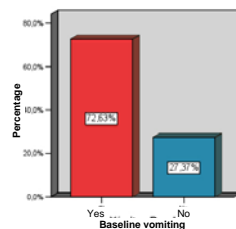


FIG. 3. PRESENCE OF VOMITING: BASELINE VS 12 H

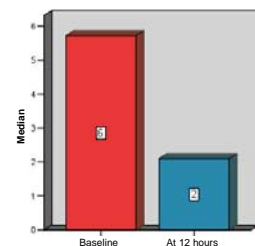
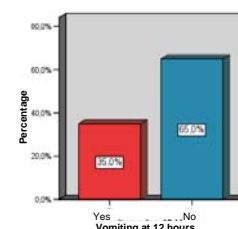


FIG. 4. NUMBER OF THE STOOLS: BASELINE VS 12 H

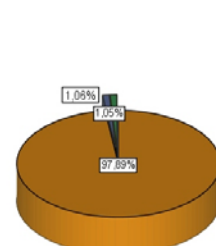
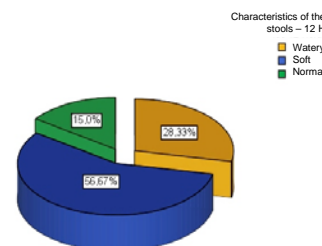


FIG. 5. CHARACTERISTICS OF THE STOOLS : BASELINE VS 12 H



## CONCLUSIONS

- The average number of stools reduced from 5,72 at baseline to 2,1 at 12 hours.
- The consistency of the stools progressed from being watery in 97,9% of the cases at baseline to 28,3% at 12
- In the first few hours after onset of the diarrhoea 72,6% of the patients had episodes of vomiting while after 12 hours of treatment, only 35% of patients were continuing to vomit (N=44).
- Weight gain was 300 grams after 12 hours of treatment.
- Body temperature reduced by 0.76°C after 12 hours of treatment, passing back below the fever threshold to normal.
- After 12 hours of treatment with oral rehydration and Gelatin Tannate, the diarrhoea in children and infants had improved significantly.