Result summary

Baseline characteristics of the study participants

The study was conducted between April 2023 and December 2024. A total of 183 patients confirmed with cutaneous leishmaniasis (CL) by microscopy were randomly assigned in a 1:1 ratio to one of two treatment arms: TT (n = 91) and IL-SSGTT (n = 92). The majority of the participants were male, comprising 49 (53.3%) in the IL-SSG and 55 (60.4%) of the TT arm. Non-ulcerated lesions were observed in 66% in the IL-SSG group and 78% of the TT group. In both arms, most patients (>75%) presented with a single lesion. The face was the most commonly affected anatomical site, with lesion observed in 87% and 83% in IL-SSG and TT group, respectively (Table 1).

Table 1: Socio-demographic and clinical characteristics for categorical (n=183)

Characteristic/Variables	IL-SSG	Thermotherapy (TT)
Gender		
Male	49(53.3%)	55(60.4%)
Female	43(46.7%)	36(39.6%)
Total	92(50.3%)	91(49.7%)
Type of Lesion		
Ulcerated	31(33.7%)	20(22%)
Non-ulcerated	61(66.3%)	71(78%)
Number of lesion(s)		
#1	69(75%)	71(78%)
#2	18(19.6%)	16(17.6%)
#>2	5(5.4%)	4(4.4%)
Total	92(50.3%)	91(49.7%)
Previous history of cutaneous leishmaniasis		
Yes	2(2.2 %)	0(0%)
No	90(97.8%)	91(100%)
Total	92 (100%)	91(100%)
Medical History		
Yes	0(0%)	3(3.3%)
No	92(100%)	88(96.7%)
Total	91(100%)	91(100%)

IL-SSG = intralesional sodium stibogluconate. TT= Thermotherapy

PRISMA flow diagram

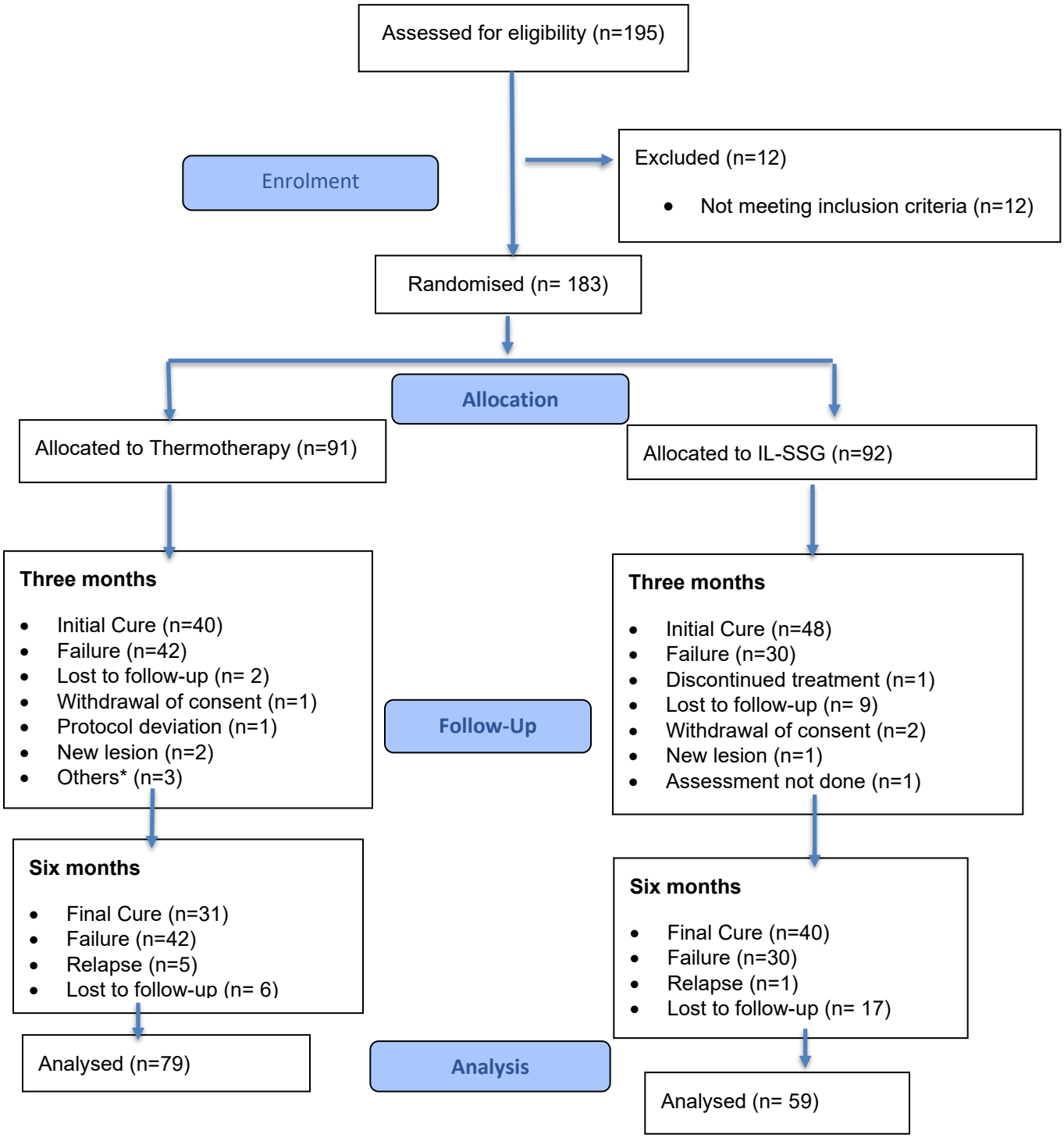

Figure 1: Study flow diagram

Treatment outcomes

One hundred eighty-three patients were included into the study.

In per protocol analysis a total of 138 (75.4%) participants were included TT(n=79) and IL-SSG (n=59). In the per protocol analysis, the initial cure at D90/105 was 36/79 (45.6%) and 59.3% (35/59) in the TT and IL-SSG arms, respectively. The final cure rate was 31 (39.2% %) for the TT and 34 (57.6%) for IL-SSG arms after 6 months follow up (Table 2).

In the ITT analysis, the initial cure rate was 40/91 (44.0%;95% CI 34.0%-54.3%, p=0.266) and 48/92 (52.2%; 95% CI 42.0%-62.4%) in the TT and IL-SSG group, respectively. The final cure rate of TT was 31/91 (34.1% ;95% CI=25.0-44.4; p=0.191). There was no significant difference in final cure rate between the two treatment arms in the ITT analysis (p=0.191) (Table 2).

Table 2: Initial and final cure rate based on per-protocol (PP) (n=138) and intention to treat analysis (ITT) (n=183)

Analysis method		Arms		P value
		TT	IL-SSG	
PP	Initial cure	45.6% (36/79)	59.3% (35/59,)	0.137
	Final cure	39.2% (31/79)	57.6% (34/59)	0.032
ITT	Initial cure	44.0% (40/91)	52.2% (48/92)	0.266
	Final cure	34.1% (31/91)	43.5% (40/92)	0.191

Safety outcomes

A total of 204 adverse events (AEs) were reported; 186 in the TT arm and 18 in the IL-SSG arm. This corresponds to 77% (70/91) of the participants in TT arm experienced AEs, compared to only 14% (13/92) in IL-SSG arm. In the TT arm, the most common AEs were localized to the application site and included pain 72/186 (38.7%), erythema 54/186 (29%), and edema 51/186 (27.4%), occurred mostly after 24 hours of TT application.

In contrast, the IL-SSG arm reported fewer and milder adverse events (AEs), primarily consisting of superinfections in 4 out of 18 participants (22%). Additionally, pain and erythema were noted in 2 out of 18 participants (11%) (table 8). All AEs in the TT arm were attributed to TT application, while only about half in the IL-SSG arm were treatment-related. Most AES were mild (grade I) and no serious complications were reported.