



TRAC Cohort 1

This was a Phase 1b study to determine the safety of CT327 ointment for four weeks to a single tumour in a CYLD mutation carrier before progressing onto cohort 2.

No blinding implementation details were carried out in cohort 1 as this was initially a phase 1b trial to determine the safety of CT327 application to a single tumour with the CYLD mutation carrier. The lack of any unexpected trial related adverse site reactions as indicated by a modified draize score of 3 or below, over a 4 week treatment period in 5 out of 8 patients will allow the study to begin recruitment of patients into cohort 2.

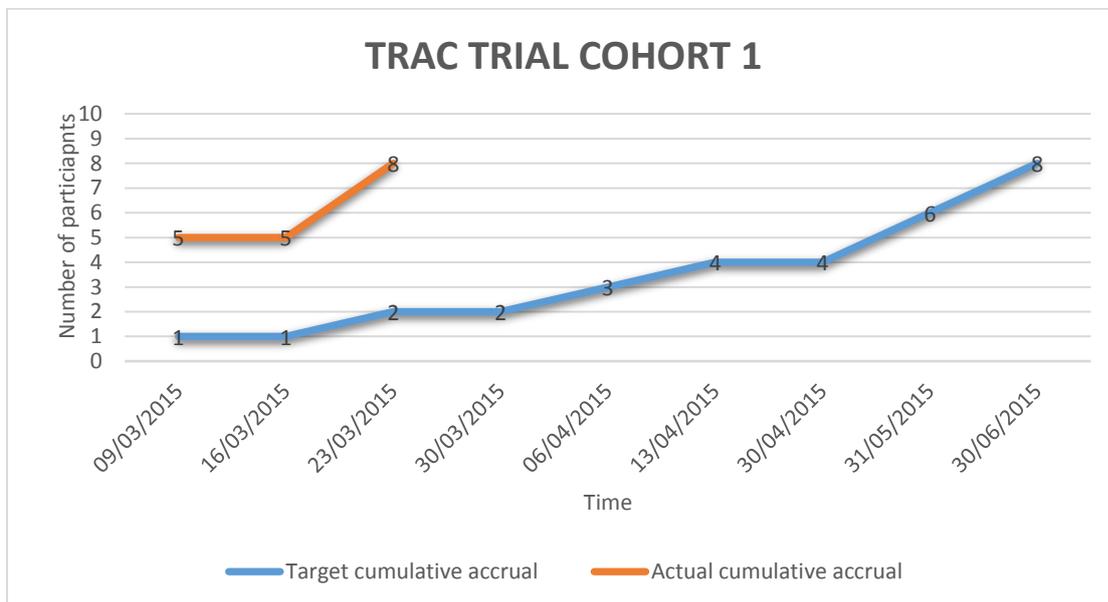


Figure 1: Cohort 1 Recruitment

Recruitment was completed ahead of schedule with all 8 participants enrolled onto the study within 1 month. Adverse events for all participants were collected within a planned 4 week treatment period. The trial was therefore able to progress onto cohort 2 on the 15/09/2015.

Table 1: Cohort 1 Baseline characteristics

	n	%
Gender		
Male	0	0
female	8	100
Ethnicity		
White	8	100
other	0	0
Age		
Median	60	
IQR	47 - 73	
Range	41 - 80	

Table 2: Cohort 1 Concomitant medications at baseline

3 participants enrolled onto the study took 1 concomitant medications, 2 participants had 4 concomitant medications. 1 participant had taken 5 concomitant medications, 1 participant had 7 concomitant medications and 1 participant took 10 concomitant medications. These medications are listed below.

Medication	No of Patients
Anti-hypertension	3
Analgesic	7
Anti-depressant/anxiety	5
Vertigo	2
Other	16

Table 3: Cohort 1 Compliance during 28 day treatment period

Compliance	n	Percent
28 days	6	75.0
27 days	1	12.5
26 days	1	12.5

Reported AE in Cohort 1:

During cohort 1, one patient developed shingles 10/04/2015. This was reported as mild and unrelated to treatment. The site of the shingles was recorded as the patient's leg, which was distant from the treatment site.

There were no SAEs reported in cohort 1.

Table 4: Cohort 1 Primary outcome

Modified Draize Score=0	n	Percent
Clear- Normal skin surface	8	100
Total	8	100