Abbreviated study report

Summary statement

This study, VAM2301 (CTAP01) was a randomized, double-blind, parallel group trial comparing the efficacy and safety of an investigational pediculicidal shampoo versus a control shampoo in the prevention of ongoing head lice infestation among family members living in a household with a confirmed index case.

In order to achieve the required statistical power, it was intended to enrol 42 index cases, along with their household members, into each arm of the study. Our original estimate was that at least 250 people would be exposed to either the investigational or control shampoo.

The study was terminated prematurely because the study supply reached the end of its shelf life. The short time window for recruitment before expiry was due to movement restrictions during the COVID-19 pandemic. There were also unanticipated consequences of lockdown restrictions; a substantial reduction in the incidence of head lice infestation and (in the early part of the recruitment period) a generalised reluctance to allow study personnel to enter subjects' homes whilst the risk of SARS-CoV-2 infection remained high.

For these reasons, only 25 primary index cases were enrolled into the study, along with 58 other household members, before termination of the study. Consequently, it is not possible to provide a full set of results or any statistical interpretation of those results. What follows is a summary of recruitment, baseline characteristics and reports of efficacy and safety data collected. Nothing should be inferred from what is reported.

Baseline characteristics

Table 1. Number of participants grouped by age cohorts.

Age	Number	Percentage	Number Index Cases	Percentage Index Cases
4-9	30	36.1	19	22.9
10-15	20	24.1	10	12.1
>15	33	39.8	5	6.0

Gender

The majority of participants (64) were females (77.1%), which is comparable with similar groups in previous studies.

Household size

Participants came from 25 households, varying in size from 3 to 8. Two households (8.0%) provided 2 participants, 14 households (56.0%) provided 3 participants, 8 households (32.0%) provided 4 participants and one household (4.0%) provided 5 participants.

Hair characteristics

Hair length was assessed as “close cropped” in 7 participants (8.4%), "above ears" in 11 participants (13.25%), "ears to shoulders" in 13 (15.7%), and “below shoulders” in 52 participants (62.65%), although styles and way of grooming varied considerably among these groupings (nearly all participants with longer hair were females). This distribution is similar to that found in previous studies.

Hair thickness was assessed as "fine" in 10 participants (12.1%), "medium" in 46 (55.4%) participants, and "thick" in 27 (32.5%) participants.

The distribution of degree of curl found 50 participants (60.2%) assessed as "straight", 29 (35.0%) as "wavy” and 4 (4.8%) as “curled”.

The distribution of hair type showed 8 participants (9.7%) assessed as "dry" and 70 (84.3%) as "normal" and 5 had (6.0%) "greasy" hair.

Infestation assessment

Of the Index Cases, both Primary* and Secondary**, 24 (70.6%) of participants were assessed as having a "light" louse infestation, 4 (11.8%) as having a "moderate" infestation and 6 (17.6%) as having a "heavy" infestation. This shows a slight trend towards lower levels of intensity of infestation than in previous studies in this population.

Previous infestations

Apart from the 23 Index Cases who only reported their current infestation as being the “last time” that they were infested, previous infestations were reported at 8 days (1 participant), 2 weeks (5 participants), 1 month (2 participants), 2 months, 3 months and 1 year (1 participant each).

Number of infestations

Within the last year, nine Index Cases said they had experienced one infestation (although the duration varied), one each reported 3, 6, and 8 infestations, 17 reported “Constant”, 3 “Regularly”, and one each “Occasional” and “Long time”.

Hair washing

In general Index Cases reported that they washed their hair at about the same frequency as other members of the household with 2 reporting 1 wash weekly; 2 washes and 3 washes a week (5 participants each); 3 reporting 4 washes; 1 reported 7 washes. Three people reported 1-2 washes, three 2-3, one 4-5 washes, 5 every other day and, one “every 2 weeks”, and 5 did not report washing frequency.

Medical history

Amongst all participants both Index Cases and other household members the most reported medical histories were asthma/pulmonary or allergic disorders (13 = 15.7%), CNS disorders (12 = 14.5%), and 4 cases each of skin disorders (eczema) and cardiology problems (hypertension), 3 ENT, 2 each

*A Primary index case was defined as the subject initially identified at screening
**A Secondary index case was defined as another member of the same household with overt signs of lice infestation at enrolment

musculoskeletal and endocrine or metabolic disorders, and 1 gastrointestinal problem and 1 "Other" in the form of spherocytosis. Apart from allergic disorders such as asthma, most of these disorders were reported by older, mainly adult, participants.

Medication

At the start of the study 19 participants (22.9%) reported using medication, largely a reflection of the high proportion of adults over 30. Over the study period there were no reported changes in medication.

Results

Presence of lice

All Primary and Secondary Index Case participants had the presence of lice confirmed at day 0. At day 3, 8/25 primary index cases and 1/8 secondary index case still had active infestation requiring an additional application of Vamousse treatment mousse. At day 6, three primary index cases and zero secondary index cases still had persistent infestation.

It was assumed that application of Vamousse Treatment Mousse on Day 0, and where necessary on Days 3 and 6, that all lice would be eliminated from Index Cases. No additional follow up of Index Cases occurred between Day 6 and Day 14. Since all Index Cases as well as other household members were directed to use the supplied shampoo, it was also expected that the investigational shampoo would also have activity to eliminate any lice that either survived exposure to or were missed during treatment with the Vamousse Treatment Mousse or that hatched from eggs unaffected by the treatment. Irrespective of whether participants were fully compliant with the planned regimen of use for the shampoo, on day 14, or as soon after as possible that a visit could be arranged, all but one of the consented participants were available for assessment. This comprised a thorough systematic combing using a plastic louse detection comb to determine the final outcome. On this day 27 (32.5%) of participants were found to be infested. This group consisted of 18 Index Cases, who presumably had not been completely cleared of their initial infestation, and 9 other household members.

Completion and withdrawal

All participants but one completed the study in relation to availability for the final check-up at Day 14 but there were various levels of withdrawal from use of the shampoo that were in some cases incorrectly recorded at the time as "Drop out". The only participant who actually dropped out from the study withdrew consent prior to starting use of the investigational product. Additionally, some participants could not be seen within the correct interval for the final checkup at Day 14. In view of the above, not all participants had complete or per protocol data sets for the following reasons:
Household 001, participants 001, 002, 003, 004: The Day 14 assessment was delayed by 13 days because the parent carer would only permit a visit by a female member of the investigation team who was unwell at the time scheduled for the Day 14 visit.
Household 006, participants 002 (B): The participant stopped using shampoo after Day 5.
Household 008, participant 001 (B): The participant stopped using shampoo after Day 4.
Household 008, participant 003 (B): The participant stopped using shampoo after Day 2.
Household 010, participant 002 (A): The participant stopped using shampoo after Day 4.
Household 013, participant 002 (B): The participant stopped using shampoo after Day 2.

Household 013, participant 003 (B): The participant lost their Diary Card.
Household 013, participants 001, 002, 003 (B): The Day 14 assessment was delayed by 6 days because the participants were not available.
Household 014, participant 001 (A): The participant stopped using shampoo after Day 1.
Household 014, participant 001 (A): The Day 14 assessment was delayed by 6 days because the participant was not available.
Household 015, participant 004 (B): The participant stopped using shampoo after Day 1.
Household 017, participants 001, 002, 003 (A): The participants lost their Diary Cards.
Household 017, participants 001, 002, 003 (A): The Day 14 assessment was delayed 10 days because the participants were not available.
Household 018, participant 001 (B): The Day 3 follow up was not performed because the participant was unwell (tonsilitis).
Household 019, participants 001, 002 (A): The Day 3 follow up was not performed because the participants were unwell with Norovirus infection.
Household 023, participant 002 (B): The participant stopped using shampoo after Day 9 because they had contracted chicken pox.
Household 023, participants 001, 002, 003 (B): The Day 14 assessment was delayed 24 days because two participants (001 and 002) were suffering from chicken pox in succession.
Household 025, participant 002 (A): The participant stopped using shampoo after Day 7.

Outcome

The primary planned outcome of the study was the proportion of individuals in each household with active head lice infestation at Day 14, with secondary objectives of demonstrating the safety and acceptability of the investigational Shampoo in daily clinical use.

The various development stages of lice recovered during the Day 14 combing using the plastic louse detection comb were all fixed into the participant's Case Record Form using clear adhesive tape so that they formed a permanent record. Each of these insects was counted and the numbers and development stages recorded in the CRF.

Following code break, it was established that of the 24 participants found to have lice at Day 14, 14/34 from 9 households were allocated the investigational shampoo and 10/25 from 7 households allocated the control shampoo. No lice were found on 8 participants from 3 households allocated the investigational shampoo and 16 participants from 6 households given the control shampoo.

The original plan for analysis of outcomes was to evaluate the effect of the shampoo treatment by the proportion of individuals with an infestation at Day 14, with outcomes stratified by household size. Since the required number of households could not be recruited within the timeframe of the study, this analysis plan could not be applied. However, based on the participant outcomes data in terms of numbers of cases of infestations relative to the numbers of households there was no detectable difference between the two treatments, with a slight trend in favour of the control shampoo.

Adverse events

Twenty participants experienced an adverse event with some participants experiencing the same event on more than one occasion. Six Index Case participants experienced a stinging or burning sensation when Vamousse Treatment Mousse was applied. One reported that some Vamousse Treatment Mousse fluid either dribbled down their forehead or else dripped from their hair into one eye during the period between application and washing off. The fluid was wiped away using a towel and the eye rinsed with water with no subsequent ill effect. Seven participants reported either a stinging or intense itching sensation either during shampoo use or immediately after. Following code break, it was possible to confirm that five of these had been allocated the control shampoo and two the investigational shampoo. Other reported adverse events were not associated with treatment and comprised two cases of chickenpox, two cases of Norovirus infection, and one case each of tonsilitis and earache.