

GNOME: 1 month measures form

DATE OF APPOINTMENT

Study ID number:

SPRAY NUMBER GIVEN:

VISIT 1 SPRAY collected Yes No 4 week diary collected Yes No

NASAL SPRAY ADHERENCE

Did your child take the spray

- Not at all Some of the time Most of the time All of the time

CHECK REFERRAL STATUS

Has your child been referred to an ENT surgeon Yes No

If yes, has the surgeon recommended surgery Yes No

If yes, do you have an appointment yet Yes No

When

CHECK ADVERSE EVENTS / SIDE EFFECTS

- | | | |
|------------------------------------------|------------------------------|-----------------------------|
| Stinging in the nose | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Nosebleed | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Dryness and irritation at back of throat | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Diarrhoea | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Cough | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If none, continue

If the patient has had a side effect that has settled they can continue with the study

If patient and/or parents are concerned about the side effects or they are severe they should be referred to the GP

OTOSCOPY *please circle:*

	Clear	RIGHT	LEFT
<i>If you suspect wax or perforation to be a problem check by using tympanometry (see Appendix 4)</i>	Wax	RIGHT	LEFT
	Perforation	RIGHT	LEFT
Child continues with study ←	Grommet	RIGHT	LEFT

TYMPANOMETRY

if **FAIL**, *please circle combination:* B + C2 or B + B

if **PASS**, *please circle combination:* A + A A + B A + C1 A + C2
C1 + B C1 + C2 C1 + C1 C2 + C2

Large amounts of wax (> 95% obscured) and a **low** compliance (< 0.2 ml) Yes No

Perforation, flat line and **high volume** (> 1.5 ml) Yes No

Please attach print out

SWEEP PURE TONE AUDIOMETRY (1 MONTH)

Performed at **25dB** in a *quiet room*

✓ = pass × = fail

	0.5 kHz	1 kHz	2 kHz	3 kHz	4 kHz
Right ear					
Left ear					

Comment: co-operative not co-operative

OPTIONAL

Appointment made with yourself or GP as part of *standard clinical care** Yes No

If yes, please specify the date(s)

**This is your standard management (i.e. further watchful waiting, antibiotics, nose drops, referral or other treatment) for glue ear which you would do or advise to the patient if the trial were not taking place.*

GNOME: adherence questionnaire

To be done 7 days after 1 month MEASURES taken

Study ID number:

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SPRAY NUMBER GIVEN:

'Hello my name is the research nurse working on the research trial your child has just entered. Would it be OK to ask a few questions about your use of the nasal spray – it should only take a few minutes. If it's inconvenient at the moment I can call back at a more convenient time. The information you give is entirely confidential.

Just to check.....'

1. Can you tell me the name of the nasal spray you were given as part of our study?

.....

2. What is the reason for using the nasal spray?

.....

3. Does your child still have the condition or problem that the nasal spray was given for?

.....

If yes, the condition / problem has improved Yes No

the condition / problem has not changed Yes No

the condition / problem has got worse Yes No

4. Has your child started taking the nasal spray? Yes No

5. How many days has your child been taking it?.....

6. How many times a day is your child taking it?.....

Please turn over

7. How many squirts do you use into each nostril each time?.....

8. How many times has your child missed taking the nasal spray?.....

9. How well do you think this spray is working for your child?

- Very well OK Not well

10. Have you any concerns or experienced any problems about your child taking this nasal spray?

a) The nasal spray has not worked / does not work Yes No

b) It gives my child unwanted effects (side effects) Yes No

c) It is difficult to give to my child Yes No

d) I worry about the long term use of this spray Yes No

e) I am concerned this spray may be harmful Yes No

f) Any other problems.....
.....

11. Would you like more information about the nasal spray or study in general? Yes No

If yes, what?.....

12. Have you experienced any difficulties with recording the symptom diary? Yes No

If yes, what?.....

13. Do you think your child is taking the active nose spray? Yes No Don't know

14. If your child had not taken the spray would you have told me? Yes No

FINALLY – do you have any comments you would like to add?.....
.....
.....

THANK YOU FOR YOUR TIME

and just to confirm your next appointment with me is on.....