

GUILLAIN-BARRE SYNDROME (GBS) BASELINE AND MONITORING TOOL - II

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number Date of Patient Visit
 mmm dd yyyy
 Protocol Number **P 1 0 8 6** Institution Code
 Form Week * Seq. No. ** Step No. Key Operator Code

* Enter a "1" if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.
 **Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

1. Was a Guillain-Barre Syndrome evaluation performed at this visit? (1-Yes, 2-No)
If No, STOP.
If Yes, continue.

2. Since the last visit, has the study participant been diagnosed with Guillain-Barre syndrome? 1-Yes
For P1086: At Screening/Entry: Has the study participant ever been diagnosed with Guillain-Barre syndrome? 2-No
 8-Not able to assess

3. Since the last visit, has a close biologic relative (parent, sibling or half-sibling, son or daughter) of the study participant been diagnosed with Guillain-Barre syndrome? 1-Yes
For P1086: At Screening/Entry: Has a close biologic relative ever been diagnosed with Guillain-Barre syndrome? 2-No
 8-Not able to assess

4. Since the last visit, have there been any new complaints of weakness in the extremities, difficulty walking or changes in strength or gait? 1-Yes, transient
For P1086: At Screening/Entry: In the past 6 months, have there been any new complaints of weakness in the extremities, difficulty walking or changes in strength or gait? 2-Yes, lasting more than 1 week
 3-No 8-Not able to assess

5. Does the study participant usually walk independently? 1-Yes
 2-No
 8-Not able to assess

REFLEXES (Awake, Not Crying):

6. Were reflexes assessed? (1-Yes, 2-No)
If No, go to question 7.
If Yes, continue.

¹ Results
1-Muscle contraction, with or without limb displacement
2-No reflex elicited
8-Not able to assess

Right ¹ Left ¹

- a. Ankle reflex
- b. Patellar reflex

<p>INSTRUCTIONS FOR EVALUATING REFLEXES:</p> <p>Ankle Reflex: With the study participant seated, the examiner uses one hand to press upward on the ball of the foot, dorsiflexing the participant's ankle to 90 degrees. Using a reflex hammer (preferably long-handled), the examiner strikes the Achilles tendon. The tendon reflex is felt by the examiner's hand as a plantar flexion of the foot, appearing after a slight delay from the time the Achilles tendon was struck.</p> <p>Patellar Reflex: Have the study participant sit with his or her legs dangling off the side of the exam table. Place your left hand on the participant's quadriceps muscle. Strike the patellar tendon firmly with the reflex hammer. Extension of the knee should be observed and a contraction of the quadriceps should be felt. Repeat the procedure in the other leg.</p>
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Pt. No. *Seq. No. **Step No. Date

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EXAMINER ASSESSMENT:

7. Since the last visit, have there been any neurologic changes or changes in lower extremity strength? 1-Yes

At Screening/Entry: In the past 6 months, have there been any neurologic changes or changes in lower extremity strength? 2-No 8-Not able to assess

If No or Not able to assess, STOP.

If Yes, continue.

a. Describe changes [140]:

DO NOT KEY:

Clinician's Signature

Date