

PROGRESS NOTE

2011-01 Protocol

Subject: Larry Alan Townsend

Date: 30-Jun-2015

Subjective:

Mr. Townsend reports today to be evaluated for the MA1331 study, protocol 2011-01. He is a 48 year old white male currently being overseen by Dr. Geoff Gillespie. His date of birth is 29-May-1967. The Version 1 consent dated 05-May-2015 was reviewed with Mr. Townsend and he was given time to ask questions and review the consent as needed. Consent was signed at 8:40 AM prior to any procedures occurring for the study. Mr. Townsend was provided with a copy of the signed consent.

Mr. Townsend indicates he has had OA in his left hip since 2000. He denies any pain in his right hip. He is currently taking Celebrex to treat his OA, but is interested in participating in a clinical trial due to his lack of insurance for prescriptions. He noted that he has never been part of an investigational drug trial. He also noted he has never received an oral corticosteroid or an intraarticular injection. Mr. Townsend noted that he has morning stiffness in his left hip for an average of about 10 minutes and then it goes away. He confirmed it has been consistent like that for the past 30 days.

Mr. Townsend confirmed that he has never had surgery on either of his hips and does not plan to have surgery during the study. He confirmed that he has never had any issues related to chronic renal failure or nephrolithiasis or any issues related to his liver. I will verify lab results for exclusion criteria related to kidney and liver function prior to visit 2. Mr. Townsend does have active GI related issues. However, per the investigator's brochure, neither the gastric reflux nor the decreased secondary peristalsis would affect his absorption of the study drug or the ibuprofen used for rescue therapy. He also confirmed that he does not have allergies to sulfa drugs.

Reviewed study related requirements with Mr. Townsend and talked again about the possibility of getting placebo. Mr. Townsend noted his understanding.

Objective:

Temp: 98.1°F by mouth, Seated BP: 115/70 mmHg, HR: 88 bpm, RR: 15 rpm, Weight: 287 pounds, Height: 69 inches. Vitals performed at 8:45 to 8:52 prior to labs being drawn. BMI calculated at 34 kg/m²

Physical exam performed. Labs drawn per protocol. Mr. Townsend noted he had not eaten since 8:30 PM on 29-Jun-2015. Therefore, labs were fasting. He noted that he expected to have labs drawn, so expected he would need to be fasting. No site staff directed him to come to the visit fasting. ECG performed per protocol.

Assessment:

Mr. Townsend meets all criteria through Visit 1 and is an appropriate candidate for the study.

Plan:

- 1) Contact Dr. Geoff Gillespie and request medical records for Mr. Townsend
- 2) Schedule x-ray with Radiological Associates
- 3) Evaluate labs and x-ray results once received
- 4) Mr. Townsend to remain taking Celebrex until notified if he meets study criteria

Electronically signed by Bill Fredericks, MD, 30-Jun-2015, 10:36 AM

BF/lmh

Physical Exam Form

2011-01 Protocol

Subject: Larry Alan Townsend

Date: 30-Jun-2015

Review of Systems:

General: Alert and awake; looks like his stated age

HEENT: Normal; zero discharge; zero lesions; TMs normal bilaterally

Skin: Normal; zero lesions

Neck: Supple, without lymphadenopathy or thyromegaly. No carotid bruits; Normal

Lymph Nodes: Not palpable, Normal

Pulmonary: Clear to A&P, Normal

Abdomen: Normal bowel sounds; zero bruits; zero tenderness; zero masses; zero guarding

Cardiovascular: Grade 1/4 diastolic murmur; zero bruits

Genitourinary: Normal

Musculoskeletal: Left side hip OA

Neurological: Decreased achilles DTR bilaterally related to diabetic neuropathy; diabetic neuropathy bilateral legs

Electronically signed by Bill Fredericks, MD, 30-Jun-2015, 12:08 PM

BF/lmh

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3001 Pavilion Drive
Houston, TX 77002
1-800-555-5555

New Pharma, LP
Protocol 2011-01

Bill Fredericks, M.D.
103 University Boulevard
University of General Studies
Anywhere, TX 78555

Accession Number: A 1 2 3 0 1 8 8	
Visit 1 – Screening	
<p>Subject Initials LAT Sex <input checked="" type="checkbox"/> M <input type="checkbox"/> F</p> <p>Date of Birth 29-MAY-1967 D D M M M Y Y Y Y</p> <p>Collection Date 30-JUN-2015 Collection Time 09:10 24 hour clock D D M M M Y Y Y Y</p> <p>Fasting (at least 8 hours without food intake)? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>The following specimens must be sent AMBIENT on the day of collection:</p> <p>Chemistry: One 7 ml serum separation tube. Gently invert the tube 6-8 times, leave upright for 30 minutes to clot. Centrifuge tube at 3000-3500 rpm for 12 minutes or until clot and serum are separated. Transfer the serum into the tube marked chemistry.</p> <p>Hematology: One 4 ml lavender top tube. Gently invert the tube 6-8 times (do not shake).</p> <p>Urinalysis: Collect a mid stream urine sample. Transfer the urine to the 10 ml yellow cap tube. Gently invert the tube 6-8 times to mix the urine with the preservative.</p> <p>ANA Analyzer Panel: One 4 ml serum separation tube. Gently invert the tube 6-8 times, leave upright for 30 minutes to clot. Centrifuge tube at 3000-3500 rpm for 12 minutes or until clot and serum are separated. Transfer the serum to the tube marked ANA analyzer panel.</p> <p>The following specimens must be sent FROZEN on the day of collection:</p> <p>Endocrinology: One 4 ml serum separation tube. Gently invert the tube 6-8 times, leave upright for 30 minutes to clot. Centrifuge tube at 3000-3500 rpm for 12 minutes or until clot and serum are separated. Transfer the serum to the tube marked Endocrinology.</p> <p>Protein Electrophoresis: One 4 ml serum separation tube. Gently invert the tube 6-8 times, leave upright for 30 minutes to clot. Centrifuge tube at 3000-3500 rpm for 12 minutes or until clot and serum are separated. Transfer the serum to the tube marked Protein Electrophoresis.</p>	
<p>Comments: DH 30-Jun-2015</p>	

LAT.
M / F
Age: 48
69. n. / 287. (b)

HR: 90 BPM

Axis:

ACCELERATED JUNCTIONAL RHYTHM
PROLONGED QT

Intervals:

QRS 90°

5.78

RR 565 ms

T 34°

P - ms

P (II) - uV

PR - ms

S (VI) -0.79 uV

QRS 88 ms

R (V5) 2.46 uV

QT 396 ms

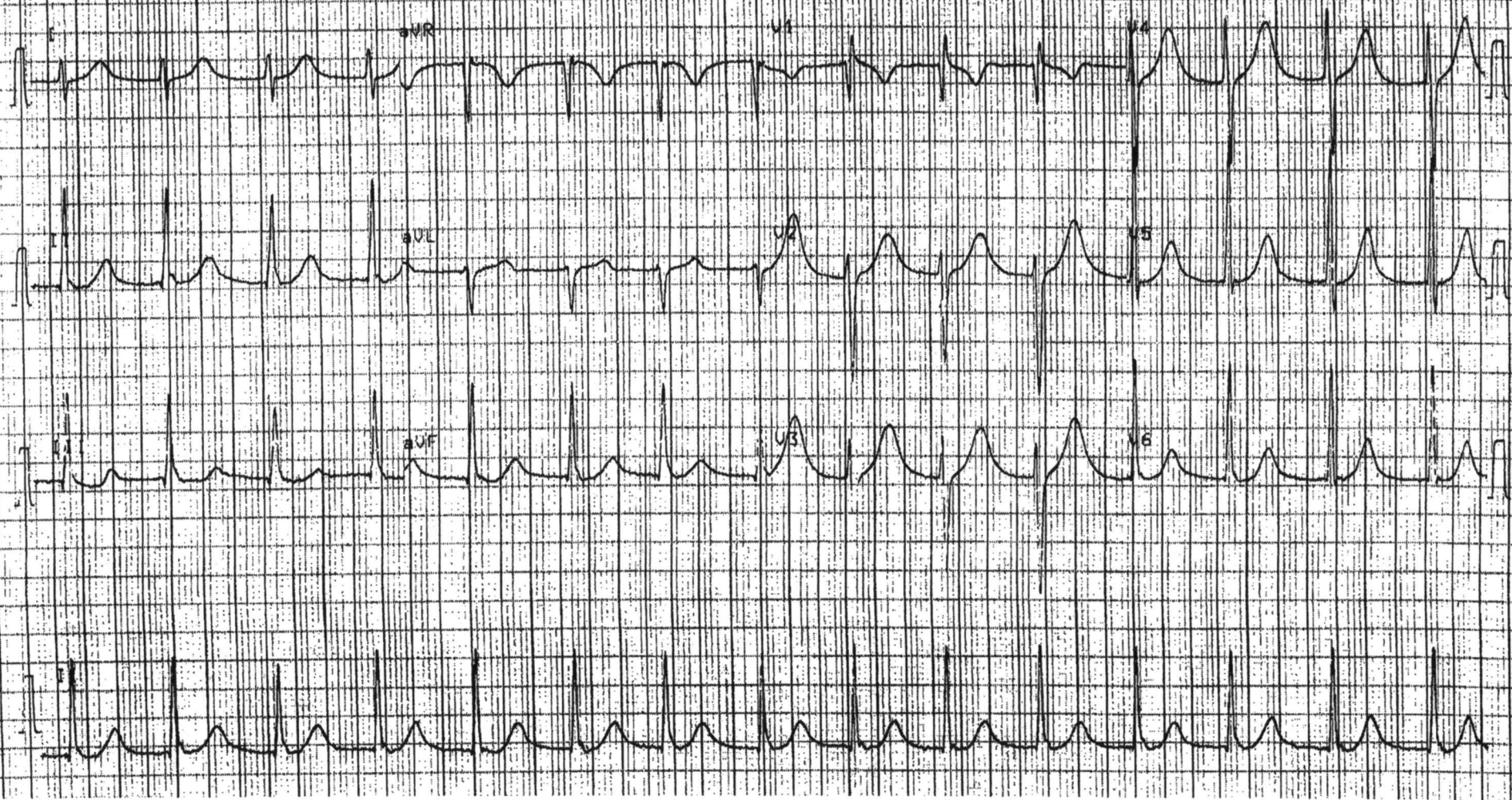
Sokol 4.02 uV

QTc 409 ms

10 mm/mV

10 mm/mV

NCS
Bill Friedman MD
30-Jun-2015
UNCONFIRMED REPORT



PROGRESS NOTE

Protocol 2011-01

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Date: 30-Jun-2015

Received medical records via fax from Dr. Geoff Gillespie's office for Mr. Larry Townsend. Reviewed medical records with Dr. Fredericks and updated case report form with all relevant information.

Contacted Mr. Townsend to let him know he was scheduled at Radiological Associates for his x-ray on 02-Jul-2015 at 9:00 am.

Electronically signed by James D. Wolf, 30-Jun-2015, 3:43 PM

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Page 1 of 4

Investigator:
Bill Fredericks, M.D.
University of General Studies
103 University Boulevard
Anywhere, TX 78555

Patient:
Initials: LAT Number: N/A
DOB: 29-May-1967 Age: 48

Protocol:
New Pharma, LP
2011-01

Visit Number: Visit 1
Collection Date: 30-Jun-2015
Collection Time: 09:10
Accession Number: A1230188
Specimen Receipt Date: 01-Jul-2015
Date of Report: 02-Jul-2015

Fasting (Yes/No): Yes

Test	Results	Units	Expected Range
Hematology:			
Hemoglobin	14	G/DL	13.0 – 17.0
Hematocrit	40.5	%	37.5 – 49.0
RBC	3.9	M/CUMM	4.1 – 5.7
WBC	6.3	K/CUMM	4.4 – 12.0
Neutrophils	53	%	42 – 72
Lymphocytes	35	%	20 – 48
Monocytes	6	%	4 – 12
Eosinophils	4.2	%	0 – 6.2
Basophils	1.5	%	0 – 2.1
Platelet Count	218	K/CUMM	135 - 420
Erythrocyte Sedimentation Rate	14	MM/Hour	0 – 15 (Men < 50 yrs)

Low
NCD
B7
10-Jul-2015

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Page 2 of 4

Investigator:

Bill Fredericks, M.D.
University of General Studies
103 University Boulevard
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Patient:

Initials: LAT Number: N/A
DOB: 29-May-1967 Age: 48

Protocol:

New Pharma, LP
2011-01

Visit Number: Visit 1

Collection Date: 30-Jun-2015

Collection Time: 09:10

Accession Number: A1230188

Specimen Receipt Date: 01-Jul-2015

Date of Report: 02-Jul-2015

Fasting (Yes/No): Yes
Test

	Results	Units	Expected Range
Chemistry:			
BUN	29	MG/DL	5 - 27
Creatinine	1.0	MG/DL	0.7 - 1.4
SGPT (ALT)	23	U/L	8 - 54
SGOT (AST)	16	U/L	5 - 34
GGT	35	U/L	15 - 85
Alkaline Phosphatase	56	U/L	32 - 130
Glucose	110	MG/DL	67 - 115
Total Cholesterol	185	MG/DL	125 - 200
LDL - Cholesterol (Calculated)	99	MG/DL	0 - 100
HDL - Cholesterol	52	MG/DL	40 - 75
TG	169	MD/DL	50 - 150

High
NCS
B7
10-Jul-2015

High
NCS
B7
10-Jul-2015

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Page 3 of 4

Investigator:
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DOB: 29-May-1967 Age: 48

Protocol:
New Pharma, LP
2011-01

Visit Number: Visit 1
Collection Date: 30-Jun-2015
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Accession Number: A1230188
Specimen Receipt Date: 01-Jul-2015
Date of Report: 02-Jul-2015

Fasting (Yes/No): Yes

Test	Results	Units	Expected Range
Urinalysis:			
Color	Yellow		Yellow
Appearance	Clear		Clear
Specific Gravity	1.0029		1.002 – 1.0035
pH	6.3		5 - 9
Leukocyte Esterase	Negative		Negative
Bilirubin	Negative		Negative
Glucose	Negative		Negative
Protein	Negative		Negative
Ketones	Negative		Negative
Blood	Negative		Negative
ANA Analyzer Panel:			
Rheumatoid Factor	14 (1:14)	IU/ML	<20 (1:20)

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New Pharma, LP
2011-01

Visit Number: Visit 1

Collection Date: 30-Jun-2015

Collection Time: 09:10

Accession Number: A1230188

Specimen Receipt Date: 01-Jul-2015

Date of Report: 02-Jul-2015

Fasting (Yes/No): Yes

Test	Results	Units	Expected Range
Endocrinology:			
Insulin	11	MCIU/ML	5 – 15
TSH	1.4	MCIU/L	0.3 – 3.0
T3 Uptake	98	NG/DL	87 – 180
Free T4	1.1	NG/DL	0.8 – 1.5
Total T4	7.3	MCG/DL	5.6 – 13.7
Serum Protein Electrophoresis:			
Total Protein	7.1	G/DL	6.2 – 8.3
Albumin	3.6	G/DL	3.0 – 5.4
% Albumin	50.7	%	N/A
Alpha-1 Globulin	0.35	G/DL	0.2 – 0.4
% Alpha-1 Globulin	4.9	%	N/A
Alpha-2 Globulin	0.8	G/DL	0.4 – 1.0
% Alpha-2 Globulin	11.2	%	N/A
Beta Globulin	1.0	G/DL	0.5 – 1.1
% Beta Globulin	14.1	%	N/A
Gamma Globulin	1.35	G/DL	0.6 – 1.5
% Gamma Globulin	19	%	N/A

Investigator Signature: Bill Fredericks Date: 10-Jul-2015

PROGRESS NOTE

Protocol 2011-01

Subject: Larry Alan Townsend

Date: 03-Jul-2015

I contacted Mr. Townsend to let him know he met all criteria in the screening process and that he should stop taking his Celebrex in preparation for returning to the office for Visit 2. He noted he had not taken his dose today, so he would not take it. Therefore, his final dose was taken on 02-Jul-2015. I let him know we had scheduled him for Visit 2 on 07-Jul-2015 at 8:00 AM.

Electronically signed by Bill Fredericks, MD, 03-Jul-2015, 1:17 PM

BF/rsm