Jun 11, 2021

Schedule of Events (Appendix 1 of "Safety and Efficacy of Imatinib for Preserving Beta-Cell Function in New-onset Type 1 Diabetes Mellitus")

In 1 collection

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 dx.doi.org/10.17504/protocols.io.bvf6n3re

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ABSTRACT

This is Appendix 1 of "Safety and Efficacy of Imatinib for Preserving Beta-Cell Function in New-Onset Type 1 Diabetes Mellitus".

This clinical study is supported by JDRF. The aim of the collection is to determine whether imatinib will slow the progression of the autoimmune destruction of ß cells and lead to the preservation of C-peptide secretion in T1DM and to assess Diabetes-related objectives and safety of Imatinib in participants with new-onset type 1 diabetes mellitus".

ATTACHMENTS

dngubkeaf.pdf

DOI

dx.doi.org/10.17504/protocols.io.bvf6n3re

PROTOCOL CITATION

Stephen.Gitelman , Jeffrey A. Bluestone 2021. Schedule of Events (Appendix 1 of "Safety and Efficacy of Imatinib for Preserving Beta-Cell Function in New-onset Type 1 Diabetes Mellitus"). **protocols.io** https://dx.doi.org/10.17504/protocols.io.bvf6n3re

COLLECTIONS

Collection of Protocols and Guidelines for Safety and Efficacy of Imatinib for Preserving Beta-cell Function in New-onset Type 1 Diabetes Mellitus

KEYWORDS

Safety, Efficacy, Imatinib, Beta-cell function, New-onset Type 1 Diabetes Mellitus

CREATED

Jun 01, 2021

Citation: Stephen.Gitelman , Jeffrey A. Bluestone (06/11/2021). Schedule of Events (Appendix 1 of "Safety and Efficacy of Imatinib for Preserving Beta-Cell Function in New-onset Type 1 Diabetes Mellitus"). https://dx.doi.org/10.17504/protocols.io.bvf6n3re

LAST MODIFIED

Jun 11, 2021

OWNERSHIP HISTORY

Jun 01, 2021 Urmilas

Jun 03, 2021 Stephen.Gitelman

PROTOCOL INTEGER ID

50398

PARENT PROTOCOLS

Part of collection

Collection of Protocols and Guidelines for Safety and Efficacy of Imatinib for Preserving Beta-cell Function in New-onset Type 1 Diabetes Mellitus

GUIDELINES

Schedule of Events

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A	B	C	D	E	F	G	H	I	J	K	L	M	N
Week	-3 to -4	0	2	4	9	13	17	22	26	39	52	78	104
Visit	-1	0	1	2	3	4	5	6	7	8	9	10	11
GENERAL ASSESSMENTS													
Informed consent	X												
Eligibility criteria	X												
Medical history	X												
Adverse events	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medications	X	X	X	X	X	X	X	X	X	X	X	X	X
Physical examination1	X	X	X	X	X	X	X	X	X				
Secondary sexual characteristics2	X	(X)	(X)										
Vital Signs	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy Monitoring (if applicable)	X	X	X	X	X	X	X	X	X	X	X		
ECG	X	X											
LABORATORY ASSESSMENTS													
Serum chemistries and liver panel3	X	X	X	X	X	X	X	X	X	X	X	X	X
Autoantibodies	X												
Hematology4	X	X	X	X	X	X	X	X	X	X	X	X	X
Infectious disease serology5	X												
PPD skin test or IGRA	X												
Urine hCG	X	X	X	X	X	X	X	X	X	X	X		
Urinalysis	X	X	X	X									
Prostate Specific Antigen (males only)	X	X	X	X									
C-peptide levels (tested from MMTT)6	X	X	X	X	X	X							

[1]Excluding genitalia unless clinically indicated

[2] The Tanner stages will be assessed at the baseline visit for every participant under 18 years of age. After the baseline visit, Tanner stages will be assessed annually on all participants who are < stage 3. If the Tanner stage is ≥3 at the baseline visit or any subsequent visit, Tanner stages will not need to be assessed at any future visit.

[3] To include sodium, calcium, potassium, chloride, phosphate, total CO2, BUN, creatinine, AST, ALT, alkaline phosphate, direct and total bilirubin.

[4] Performed locally; to include CBC with differential and platelets.

[5] Hepatitis B and C, HIV, toxoplasmosis, VZV, EBV, and CMV serology. CMV/EBV PCR testing may be obtained (centrally) or locally, if necessary to confirm active infection.

[6] 4-hour MMTT at Visits -1, 9, 11 and 2-hour MMTT at Visits 4, 7, and10.

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A	B	C	D	E	F	G	H	I	J	K	L	M	N
Week	-3 to -4	0	2	4	9	13	17	22	26	39	52	78	104
Visit	-1	0	1	2	3	4	5	6	7	8	9	10	11
Plasma Glucose (tested from MMTT)5	X	X	X	X	X	X							
HbA1C levels	X	X	X	X	X	X	X						
STUDY DRUG ADMINISTRATION													
Study drug administration	X	X	X	X	X	X	X						
Study drug compliance	X	X	X	X	X	X	X						
DISEASE SPECIFIC ASSESSMENTS													
Glucose (Glucometer Reading)	X	X	X	X	X	X	X	X	X	X	X	X	
Insulin use	X	X	X	X	X	X	X	X	X	X	X	X	
Hypoglycemia assessment	X	X	X	X	X	X	X	X	X	X	X	X	
Serum-Adiponectin7	X	X	X	X	X								
Plasma-Glucagon6	X	X	X	X	X	X							
Plasma-Proinsulin6	X	X	X	X	X	X							
BONE AND MINERAL METABOLISM													
Serum Calcium8	X	X	X	X	X								
Serum Phosphate7	X	X	X	X	X								
PTH	X	X	X	X	X								
25-OH Vitamin D	X	X											
Serum CTX9	X	X	X	X									
Osteocalcin8	X	X	X	X									
GROWTH RATE ASSESSMENTS10													
Plain Radiograph of Left Hand	X	X11	X10										
Height by Stadiometer12	X	X	X	X	X	X	X	X	X	X	X	X	X
Arm span	X	X	X	X									

[7] Samples will be archived for potential future testing.

[8] Tested as part of serum chemistry panel.

[9] Samples will be archived and tested if clinically indicated.

[10] To be performed on growing-age participants per Section 5.2.9.

[11] Bone age will be assessed annually until epiphyses are near complete closure (98% of mature height at bone age of 15 yrs 9 months for boys, 14 yrs for girls).

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[12] Subjects will need to be measured with a wall mounted stadiometer to insure accurate height measurements.

A	B	C	D	E	F	G	H	I	J	K	L	M	N
Week	-3 to -4	0	2	4	9	13	17	22	26	39	52	78	104
Visit	-1	0	1	2	3	4	5	6	7	8	9	10	11
IGF-1, IGF-BP3, LH, FSH, Estradiol (females), Testosterone (males)13	X	X	X	X									
Total IgA	X14												
TSH and T4	X13	X15	X14										
Tissue transglutaminase (IgA)16	X13	X14	X14										
MECHANISTIC ASSAYS													
Serum-Autoantibody Analysis	X	X	X	X	X	X							
PBMC-Flow Cytometry Panel Staining	X	X	X	X	X	X							
PBMC-Cell Based Assays	X	X	X	X	X	X							
PBMC-Genomics, Proteomics	X	X	X	X	X	X							
PBMC- FOXP3 Methylation Assay	X	X	X	X	X	X							
Whole Blood-Gene Expression Profiling	X	X	X	X	X	X							
Whole Blood DNA-HLA Genotypes	X	X	X										
Plasma-Archive	X	X	X	X	X	X							
Serum- Beta Cell Death Assay	X	X	X	X	X	X	X						
Serum-Cytokines	X	X	X	X	X	X							

[13] Samples will be archived and tested if clinically indicated.

[14] Tested at Baseline only if not tested by referring physician within 3 months prior to Baseline.

[15] Samples will be collected at Visits 9 and 11 only if clinically indicated in growing age participants. If required, testing will be performed real-time.

[16] Performed locally.

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