

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0087	Subject Initials :XPT	DOB :06/15/1988	Sex:Female	Race:Asian	Height:158cm	Weight:57.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/02/2015	06/05/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description:Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition		Start Date	Related to study condition	Ongoing		
Hysteroscopy normal		Uk-Mar-2015	Not on treatment/medication			

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NA/EMR700623-541/C02-0087

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Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0102	Subject Initials :HYD	DOB :10/14/1985	Sex:Female	Race:Asian	Height:163cm	Weight:57.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/19/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/04/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description: Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
Palace laparoscopy				Uk-Unk-2013	Not on treatment/medication	

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Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0103	Subject Initials :CPZ	DOB :05/12/1989	Sex:Female	Race:Asian	Height:165cm	Weight:63.5kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/19/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/05/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description: Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
The right side of the open line on the right side of salpingectomy tubal pregnancy				Uk-Unk-2011	Not on treatment/medication	

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Non Serious Adverse Drug Reactions Report

Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0137	Subject Initials :YLF	DOB :11/01/1989	Sex:Female	Race:Asian	Height:153cm	Weight:47.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/22/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/09/2015	06/16/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description: Moderate OHSS occurs canceled embryo transfer, OHSS improvement						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction				Uk-Unk-2014	Not on treatment/medication	

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Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0138	Subject Initials :TTJ	DOB :06/20/1990	Sex:Female	Race:Asian	Height:150cm	Weight:41.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/22/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/06/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	None	Resolved		
Event Description: Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
Ectopic pregnancy laparoscopic surgery: the right fallopian tube embryo pelvic sticking points				Uk-Jan-2014	Not on treatment/medication	
Hysteroscopy: endometrial polyps.				Uk-Feb-2015	Not on treatment/medication	

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Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0164	Subject Initials :AHC	DOB :12/12/1982	Sex:Female	Race:Asian	Height:156cm	Weight:49.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/26/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/12/2015	06/20/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description:Moderate OHSS occurs canceled embryo transfer, OHSS improvement						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
HSG: bilateral tubal occlusion side				Uk-Unk-2012	Not on treatment/medication	
Laparoscopy Surgery: salpingostomy, pelvic adhesions dissection.				Uk-Unk-2012	Not on treatment/medication	

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Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02		
Subject No :C02-0176	Subject Initials :KBF	DOB :05/19/1986	Sex:Female	Race:Asian	Height:160cm Weight:57.0kg
First administration date of batch :			Batch number :		
Study Drug	Start Date	Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/27/2015	200			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/11/2015	06/17/2015		Related	Moderate
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest AE dose limiting toxicity
None(Othervalue:)		Not applicable	None	Resolved	
Event Description:OHSS occurs not put embryos					
Subject received concomitant medications:					
Does the subject have any relevant past or present medical conditions:Yes					
Condition			Start Date	Related to study condition	Ongoing
Tubal examination: passable			Uk-Unk-2008	Not on treatment/medicatio n	
HSG: bilateral tubal occlusion			Uk-Unk-2009	Not on treatment/medicatio n	
Laparoscopy surgery: bilateral tubal repair plastic surgery, pelvic adhesions dissection			Uk-Unk-2011	Not on treatment/medicatio n	
Ectopic pregnancy: open surgery			Uk-Unk-2012	Not on treatment/medicatio n	

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NA/EMR700623-541/C02-0176

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Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0178	Subject Initials :XSC	DOB :10/11/1988	Sex:Female	Race:Asian	Height:155cm	Weight:54.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/27/2015	200				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/10/2015	06/16/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description: Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
HSG: bilateral tubal resistance.				Uk-Jan-2013	Not on treatment/medication	
Laparoscopy surgery: pelvic adhesions dissection, bilateral salpingo-repair plastic surgery, normal uterine shape.				Uk-Jan-2013	Not on treatment/medication	
Hysteroscopy normal, water surgery: incomplete right fallopian tube obstruction				Uk-Feb-2015	Not on treatment/medication	

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NA/EMR700623-541/C02-0178

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Start Date:2016-08-15 End Date:2016-08-16

Study :EMR700623-541	Investigator :NA	Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-036	Subject Initials :JSY	DOB :07/28/1981	Sex:Female	Race:Asian	Height:162cm	Weight:54g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	03/13/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/24/2015	04/07/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Concomitant medication **	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

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